

Exhibit D

Robert D. Moore, D.O.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC.,) Master File No.
PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY) MDL 2327
LITIGATION)
) JOSEPH R. GOODWIN
) U.S. DISTRICT JUDGE
)
THIS DOCUMENT RELATES TO)
THE FOLLOWING CASES IN)
WAVE 1 OF MDL 200:)
)
)
Angela Coleman, et al. v.)
Ethicon, Inc., et al.)
Civil Action No.)
2:12-cv-01267)
)
)
Mary F. Cone v.)
Ethicon, Inc., et al.) DEPOSITION OF
Civil Action No.) ROBERT D. MOORE, D.O.
2:12-cv-00261)
)
)
Teresa Georgilakis, et al.)
v. Ethicon, Inc., et al.)
Civil Action No.)
2:12-cv-00829) April 15, 2016
)
)
Dawna Hankins v. Ethicon,)
Inc., et al.)
Civil Action No.)
2:12-cv-00369)
)
)
Margaret Kirkpatrick v.)
Ethicon, Inc., et al.)
Civil Action No.)
2:12-cv-00746)
)
)
Carrie Smith v. Ethicon,)
Inc., et al.)
Civil Action No.)
2:12-cv-00258)

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1 Isabel Swint v. Ethicon,) 2 Inc., et al.) 2 Civil Action No.) 2 2:12-cv-00786) 3) 4 5 6			1 CONTENTS 2 THE WITNESS: ROBERT D. MOORE, D.O. 3 EXAMINATION Page 4 By Ms. Maimbourg 6 5 6 EXHIBITS 7 8 Exhibit Description Page 9 Exhibit 1 Report of Robert Moore 6 10 Exhibit 2 Notice of deposition 15 11 Exhibit 3 Curriculum vitae attached to 12 report 18 13 Exhibit 4 Curriculum vitae brought by Moore 18 14 Exhibit 5 Updated list of cases with Moore 15 depositions 8 16 Exhibit 6* Thumb drive 17 17 Exhibit 7 Reliance list 20 18 Exhibit 8 Chart labeled Potential Risks of 19 Non-Mesh SUI Surgery 41 20 Exhibit 9 Document titled Potential Risks 21 of Non-Mesh and Mesh SUI 22 Surgeries 49 23 Exhibit 10 Abstract presented at American 24 Urogynecology Society meeting, 2014 51 23 Exhibit 11 Sub-analysis of data from 24 abstract 51		
7 8 9 April 15, 2016 10 9:42 a.m. 11 12 13 14 15 16 Suite 1560 17 3575 Piedmont Road, N.E. 18 15 Piedmont Center 19 Atlanta, Georgia 20 21 22 23 24 Reported by: F. Renee Finkley, RPR, RMR, CRR, CLR, CCR-B-2289					
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1 APPEARANCES OF COUNSEL 2 3 On behalf of the Defendants 4 Ethicon, Inc. and Johnson & Johnson: 5 RITA A. MAIMBOURG, ESQ. 6 Tucker Ellis, LLP 7 Suite 1100 8 950 Main Avenue 9 Cleveland, Ohio 44113 10 (216) 592-5000 11 rita.maimbourg@tuckerellis.com 12 13 On behalf of the Plaintiffs: 14 BRITTANY T. MARIGLIANO, ESQ. 15 Blasingame, Burch, Garrard & Ashley, P.C. 16 440 College Avenue 17 Suite 320 18 Athens, Georgia 30601 19 (706) 354-4000 20 btm@bbgbalaw.com 21 22 23 24			1 EXHIBITS 2 Exhibit Description Page 3 4 Exhibit 12 Study classifying patients with 5 mesh complications 52 6 Exhibit 13 Website page from International 7 Center For Laparoscopic 8 Urogynecology 53 9 Exhibit 14 ACOG and AUGS Practice Bulletin 10 on Urinary Incontinence in Women, 11 dated November 5th, 2015 62 12 Exhibit 15 Document titled Position 13 Statement on Mesh Midurethral 14 Slings For Stress Urinary 15 Incontinence 66 16 17 Exhibit 16 Document titled Frequently Asked 18 Questions By Providers, 19 Midurethral Slings For Stress 20 Urinary Incontinence 68 21 Exhibit 17 Document regarding trial by Teo 82 22 Exhibit 18 Article by Hinoul 95 23 Exhibit 19 Article by Collinet 101 24 Exhibit 20 Weisberg memo 120 23 *(Exhibit 6 was retained by counsel for 24 Defendants.)		

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1 (Exhibit 1 was marked for 2 identification.)	1 where your signature is, you have a list of nine 2 cases where you have given depositions, correct?
3 ROBERT D. MOORE, D.O., 4 having been first duly sworn, was examined and 5 testified as follows:	3 A. Yes, and we've given you an updated 4 version of that right there (indicating).
6 EXAMINATION	5 (Exhibit 5 was marked for 6 identification.)
7 BY MS. MAIMBOURG:	7 Q. (By Ms. Maimbourg) And I've marked that 8 as Exhibit 5. Is that what you brought today with 9 you?
8 Q. Good morning, Doctor. Could you state 9 your name?	10 A. Yes.
10 A. Robert D. Moore.	11 Q. I haven't looked at it closely, but the 12 nine cases that are on Exhibit 1, I believe are also 13 on Exhibit 5?
11 Q. And Dr. Moore, I have marked as Exhibit 1 12 a copy of the report that was served on us in this 13 case, and I'd like you to take a look at it and 14 identify it as the report you have prepared for this 15 litigation?	14 A. Yes, they should be.
16 A. Yes, it appears to be.	15 Q. In these -- let's just stick to the nine 16 cases that were in your report. Those were cases in 17 which you were designated as an expert witness?
17 Q. And that your signature on page 42?	18 A. Yes. One of them may have been a treating 19 physician. Ms. Teague might have been a treating 20 physician.
18 A. Yes.	21 Q. As to the other eight, though, you believe 22 you were identified as an expert?
19 Q. Dated January 21st of 2016?	23 A. Yes.
20 A. Yes.	24 Q. And in those depositions, did you testify
21 Q. Doctor, the purpose of the deposition 22 today is for me to get a full understanding of your 23 opinions as stated in your report. Do you understand 24 that that's why we're here?	Page 7
1 A. Yes.	Page 9
2 Q. Are you prepared to do that?	1 that the plaintiffs injuries were caused by the 2 various mesh implants that these plaintiffs had?
3 A. Yes.	3 A. Yes.
4 Q. What did you do to prepare for the 5 deposition?	4 Q. Did you testify in any of those cases, the 5 eight cases we're talking about, that the devices 6 implanted were defective in some way?
6 A. Reviewed my report, reviewed pertinent 7 internal documents from Ethicon that I reviewed, 8 depositions, reviewed the literature, as well met 9 with Jim Matthews on two occasions. Once last week 10 for about two hours, once this week for about an 11 hour, and then also just met with Brittany this 12 morning for about a half-hour.	7 A. Yes, I believe I did.
13 Q. In connection with preparing this report 14 that's marked as Exhibit 1, did you look at the 15 medical records of any plaintiff making claims 16 against Ethicon?	8 Q. Now, in terms of depositions or trial 9 testimony since 2013, which is basically where this 10 list ends, Exhibit 5 would include all of those, 11 right?
17 A. Not for this report, no.	12 A. Yes.
18 Q. So if your report was served in seven 19 cases, and I won't name them, because they're on the 20 notice, would it be fair to say that you have no 21 opinions about any of the alleged injuries of those 22 plaintiffs?	13 Q. And it looks like since 2014 -- and I 14 apologize, I can't show this to you while I'm looking 15 at it, you've given -- looks like another eight 16 depositions in cases at the request of the Potts Law 17 Firm; does that sound right?
23 A. Correct.	18 A. Yes and I don't think -- some of those 19 were combined depositions, so there were -- you know, 20 there may have been two depositions to cover those 21 particular patients. Multiple patients were in like, 22 for example, one deposition.
24 Q. On your report, specifically on page 42,	23 Q. Would those be in the Mentor cases or the 24 Bard cases?

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<p style="text-align: center;">Page 10</p> <p>1 A. Mentor cases, as well the Bard cases. 2 Q. What does it mean when you have here 30 Q 3 deposition? 4 A. So there was a couple patients that the 5 judge deemed that -- I think it was a second wave or 6 a third wave -- that the deposition was going to be 7 by question and answer, written questions and 8 answers. So the questions were just posed, and then 9 I had to answer those questions in a deposition type 10 of a situation. 11 Q. In a written -- 12 A. It wasn't written, no. They gave us the 13 written questions ahead of time. Then we showed up 14 and we just answered those 30 questions. 15 Q. Sounds interesting. 16 MS. MARIOLIANO: That was wave 3 of the 17 Bard cases. 18 THE WITNESS: Answered the same questions 19 over and over again for each patient. It 20 was -- 21 Q. (By Ms. Maimbourg) So in all of these 22 cases, whether on Exhibit 1 or Exhibit 5, if Bard is 23 named, or Mentor is named, or Boston Scientific is 24 named, in those cases, other than the Teague case,</p>	<p style="text-align: center;">Page 12</p> <p>1 Q. Any of those other cases involve TOT 2 slings? 3 A. In the remaining of these cases, I don't 4 know if they had a TOT sling or not at the time of 5 the procedure. The rest of them definitely had 6 prolapse products as well. 7 Q. Have you ever testified in a case where 8 the plaintiff alleged medical malpractice? 9 A. As an expert, no. Wait a minute, yes. 10 Q. How long ago was that? 11 A. Just a few weeks ago. 12 Q. Okay. What was the issue in that case? 13 A. The issue -- I was defending a physician. 14 And the issue was a complication after a TVT sling. 15 Q. What was the complication? 16 A. Complication was a large hematoma that 17 occurred after the sling and subsequent pain from 18 that. 19 Q. And what's the name of that plaintiff? 20 A. I can get that for you. Let me think one 21 second. Ball versus Kumar. 22 Q. Kumar is K-U-M-A-R? 23 A. Yes. 24 Q. Where is that pending?</p>
<p style="text-align: center;">Page 11</p> <p>1 where you may have just been a treater, you were 2 always testifying as an expert witness? 3 A. Yes. 4 Q. Do you know which of them involved a sling 5 product? And feel free to look at 5 and 1. 6 A. So the Teague was a sling, and then the 7 ones that say Align -- I don't know if the 8 combinations -- so the ones that say just Align on 9 The Potts Law Firm, Crawford, Earles, Laychak, 10 Richard, that was sling product. Bambi Teague was 11 Obtryx; that was a sling. The Boston Scientific both 12 were -- one was -- one was a combo case of a sling 13 and a prolapse, and one was just a sling. 14 Q. Were any of the products transobturator 15 slings? Is Align a transobturator? 16 A. No, Align was not. 17 Q. How about Obtryx? 18 A. Obtryx is, yes. 19 Q. So you've testified in at least one case 20 where Obtryx was at issue or more than one? 21 A. One was a treating physician, and then 22 one, it appears, was a -- was as an expert. 23 Q. And the name of that case is what? 24 A. That was Allen versus Boston Scientific.</p>	<p style="text-align: center;">Page 13</p> <p>1 A. It was just settled in Florida. 2 Q. They settled it after your deposition? 3 A. Yes. 4 Q. You were testifying on behalf of the 5 physician? 6 A. Yes. 7 Q. Was the gist of your opinion that this 8 complication was a known risk? 9 A. Yes. 10 Q. And your further opinion was, is that 11 because it was a known risk, and he met the standard 12 of care, there was no liability? 13 A. Correct. And it was a "she." 14 Q. Sorry. Gender bias. In terms of your 15 compensation for your medical/legal work, on page 42 16 of your report, you list what your charges are. Are 17 those accurate? 18 A. Yes. 19 Q. So is a three-hour deposition a half day? 20 A. Yes. 21 Q. Your report is quite lengthy and detailed. 22 Would you agree with me? 23 A. Yes. 24 Q. Did you use a research assistant?</p>

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<p>1 A. No.</p> <p>2 Q. How did you put it together?</p> <p>3 A. I've written many reports in the previous</p> <p>4 cases that I've been involved with, so I used those</p> <p>5 as somewhat of a skeleton framework. And then just</p> <p>6 went through step by step with reviewing the</p> <p>7 literature, reviewing internal documents, reviewing</p> <p>8 depositions, and that sort of thing to ultimately put</p> <p>9 it together.</p> <p>10 Q. How many hours did you spend preparing</p> <p>11 your general report?</p> <p>12 A. I would estimate a couple hundred.</p> <p>13 Q. Does that mean 200 or more?</p> <p>14 A. 200 or more, yeah.</p> <p>15 Q. And you charged for that \$1,000 per hour?</p> <p>16 A. Yes.</p> <p>17 Q. And since my math is really bad, is</p> <p>18 that -- you've charged at least \$200,000 for</p> <p>19 preparing this report?</p> <p>20 A. I haven't charged anything yet. I have</p> <p>21 not invoiced anything yet, but I will, yes.</p> <p>22 Q. When do you plan to invoice it?</p> <p>23 A. Probably within the next few weeks.</p> <p>24 Q. Do you have an arrangement where you are</p>	<p>1 things, so before we started, Brittany handed me a</p> <p>2 couple of your articles. These were the abstracts</p> <p>3 and then your publication called the IUGA/ICS</p> <p>4 classification, et cetera, et cetera. You brought</p> <p>5 those three --</p> <p>6 A. Yes.</p> <p>7 Q. -- right? And then you brought two</p> <p>8 binders, and I don't care whether Brittany or you</p> <p>9 explain what's in them on the record, but I just want</p> <p>10 to know on the record what they are.</p> <p>11 A. Sure. These are just all of the</p> <p>12 references, basically, throughout the report.</p> <p>13 Q. And they include both internal documents</p> <p>14 and medical literature?</p> <p>15 A. Yes.</p> <p>16 Q. If I asked you to find a particular</p> <p>17 article when we're going through the deposition</p> <p>18 today, how easy is it going to be for you, because I</p> <p>19 notice there's not an index?</p> <p>20 A. Well, they are -- these are indexed, and I</p> <p>21 know what's in this, so relatively easily, yes.</p> <p>22 Q. I'm not going to do it a lot, but there</p> <p>23 may be a few that I'm going to ask you to reference?</p> <p>24 A. It should just take a minute.</p>
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<p>1 paid a contingency?</p> <p>2 A. No.</p> <p>3 Q. It's a straight hourly arrangement, right?</p> <p>4 A. Yes.</p> <p>5 Q. And who do you have that arrangement with?</p> <p>6 A. Jim Matthews.</p> <p>7 Q. Do you have a written contract?</p> <p>8 A. No.</p> <p>9 Q. So you've been paid nothing as of today's</p> <p>10 date for the preparation of this report?</p> <p>11 A. Correct.</p> <p>12 Q. Once you invoice Mr. Matthews, are you</p> <p>13 willing to provide a copy of your invoice to me?</p> <p>14 A. Certainly.</p> <p>15 (Exhibit 2 was marked for</p> <p>16 identification.)</p> <p>17 Q. (By Ms. Maimbourg) Doctor, I'm going to</p> <p>18 hand you Exhibit 2, which is the notice of</p> <p>19 deposition. Have you seen this before today?</p> <p>20 A. Yes.</p> <p>21 Q. And you understand that it asks you to</p> <p>22 bring certain documents, right?</p> <p>23 A. Yes.</p> <p>24 Q. And it looks like you did bring some</p>	<p>1 Q. And it looks like you brought a copy of</p> <p>2 your reliance list, right?</p> <p>3 A. Yes.</p> <p>4 Q. We're going to mark that. Is there -- and</p> <p>5 you brought this list of testimony. Is there</p> <p>6 anything else you brought, other than this thumb</p> <p>7 drive?</p> <p>8 A. No, I don't think so.</p> <p>9 MS. MARIGLIANO: He brought a copy of his</p> <p>10 report, but --</p> <p>11 Q. (By Ms. Maimbourg) And the CV?</p> <p>12 A. Yes.</p> <p>13 MS. MARIGLIANO: And the CV.</p> <p>14 MS. MAIMBOURG: Okay. So we're going to</p> <p>15 mark this thumb drive as Exhibit 6, but I'm only</p> <p>16 going to do it in a virtual way, and ask you to</p> <p>17 identify what Exhibit 6 is.</p> <p>18 (Exhibit 6 was marked for</p> <p>19 identification.)</p> <p>20 THE WITNESS: There's a thumb drive that</p> <p>21 has everything that Jim Matthews and the law</p> <p>22 firm sent to me.</p> <p>23 MS. MAIMBOURG: And, Brittany, is it --</p> <p>24 can you agree that I may take this with me and</p>

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<p style="text-align: right;">Page 18</p> <p>1 not give it to the court reporter?</p> <p>2 MS. MARIGLIANO: Yes, that's fine. Thank</p> <p>3 you.</p> <p>4 Q. (By Ms. Maimbourg) All right. So I'm</p> <p>5 just going to ask very few questions about the notice</p> <p>6 of deposition. You were asked to bring information</p> <p>7 about your billing, and we've already talked about</p> <p>8 that, you haven't invoiced yet, right?</p> <p>9 A. Correct.</p> <p>10 (Exhibit 3 and Exhibit 4 were marked</p> <p>11 for identification.)</p> <p>12 Q. (By Ms. Maimbourg) In terms of your CV,</p> <p>13 I'm going to mark -- well, I've marked -- this is the</p> <p>14 CV, Exhibit 3, that was attached to your report as</p> <p>15 Exhibit A. And then today, you've brought what I've</p> <p>16 marked as Exhibit 4. And can you tell me if there's</p> <p>17 any significant difference between the two of those?</p> <p>18 A. I don't think so, but I just wanted to</p> <p>19 make sure that we had the most recent one. I think I</p> <p>20 noticed this one was updated December 2015, at least</p> <p>21 it's noted that, but when I talked to my assistant,</p> <p>22 she thought she probably had updated it more</p> <p>23 recently, but didn't change -- or wasn't sure, but</p> <p>24 didn't change the date, so I said give me the one</p>	<p style="text-align: right;">Page 20</p> <p>1 A. In the -- this Ethicon MDL?</p> <p>2 Q. Yes.</p> <p>3 A. I believe I just read one. I think I read</p> <p>4 Neeraj Kohli's after they were all submitted.</p> <p>5 Q. Do you know Dr. Kohli?</p> <p>6 A. I do.</p> <p>7 Q. Did you say you read it after all the</p> <p>8 reports were submitted?</p> <p>9 A. Yes.</p> <p>10 Q. Why is it that you read that one?</p> <p>11 A. Because it was a TVT-O document.</p> <p>12 Q. Anything in there that you remember or</p> <p>13 that you agree with or disagree with?</p> <p>14 A. I do not -- I don't remember. I don't</p> <p>15 think there was anything that I didn't agree or</p> <p>16 disagreed with.</p> <p>17 (Exhibit 7 was marked for</p> <p>18 identification.)</p> <p>19 Q. (By Ms. Maimbourg) Doctor, I've marked</p> <p>20 Exhibit 7, and this is -- was part of your report and</p> <p>21 this essentially is your reliance list; is that true?</p> <p>22 A. Yes.</p> <p>23 Q. And how, specifically, was that prepared?</p> <p>24 MS. MARIGLIANO: My office prepared this,</p>
<p style="text-align: right;">Page 19</p> <p>1 that's -- that we have as the most recent.</p> <p>2 Q. You do a lot of speaking and publishing,</p> <p>3 so I assume your CV is updated --</p> <p>4 A. Yes.</p> <p>5 Q. -- quite often?</p> <p>6 A. Yes. So I don't think there's anything</p> <p>7 different on this one than the one you have, but I</p> <p>8 just wanted to bring --</p> <p>9 Q. Why don't you hand me the two CVs. I'm</p> <p>10 going to stick them in this stack right here. I may</p> <p>11 get back to those later. And then in terms of the</p> <p>12 notice, Number 5 asked you to bring a complete list</p> <p>13 of the cases in which you testified, and we've</p> <p>14 already discussed that, right?</p> <p>15 A. Yes.</p> <p>16 Q. Schedule -- the schedule to this</p> <p>17 paragraph 16 asks you to bring documents relating any</p> <p>18 communication involving you and any of the</p> <p>19 plaintiffs' other experts. Do you have any such</p> <p>20 documents?</p> <p>21 A. I do not.</p> <p>22 Q. Have you read any of the general experts'</p> <p>23 reports that have been proffered at any time in this</p> <p>24 MDL by plaintiffs against defendants?</p>	<p style="text-align: right;">Page 21</p> <p>1 the list.</p> <p>2 MS. MAIMBOURG: You mean typed it?</p> <p>3 MS. MARIGLIANO: Yes.</p> <p>4 MS. MAIMBOURG: So -- thank you.</p> <p>5 Q. (By Ms. Maimbourg) The F mesh documents,</p> <p>6 meaning the internal Ethicon documents here, they</p> <p>7 were provided to you by the plaintiffs' firm, right?</p> <p>8 A. Yes.</p> <p>9 Q. By Mr. Matthews' firm?</p> <p>10 A. Yes.</p> <p>11 Q. Did you list here everything that they</p> <p>12 sent you?</p> <p>13 A. I believe so, yes. They listed -- they</p> <p>14 prepared this and --</p> <p>15 MS. MARIGLIANO: I will represent to you</p> <p>16 that it's my understanding that all of the</p> <p>17 Ethicon documents that we sent to him are listed</p> <p>18 in this document.</p> <p>19 MS. MAIMBOURG: Okay. Thanks.</p> <p>20 Q. (By Ms. Maimbourg) Doctor, do you</p> <p>21 recognize that by relying on internal documents</p> <p>22 selected by somebody else, that you may not have a</p> <p>23 totally objective view of certain things?</p> <p>24 MS. MARIGLIANO: Object to the form.</p>

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<p>1 THE WITNESS: I'm not sure I understand 2 the question.</p> <p>3 Q. (By Ms. Maimbourg) Okay. So you did not 4 ask for or obtain access to Ethicon's entire global 5 production, have you?</p> <p>6 A. No, I did not.</p> <p>7 Q. Have you read every single deposition of 8 every Ethicon employee taken in the MDL? I hope not.</p> <p>9 A. No, I don't believe I have.</p> <p>10 Q. So to be fair, your review of the Ethicon 11 story, which is contained in the depositions and 12 documents that you were provided, is not a complete 13 story. Would you agree with that?</p> <p>14 MS. MARIGLIANO: Object to the form.</p> <p>15 THE WITNESS: I would agree that there's 16 documents that I've not seen from either 17 internal documents or depositions, as you've 18 said. So I've relied on -- the only internal 19 documents I've seen, I've relied on the law firm 20 providing me that, yes.</p> <p>21 Q. (By Ms. Maimbourg) So you're relying on a 22 law firm representing plaintiffs who claim they are 23 injured to provide you with documents to form your 24 opinions?</p>	<p>1 Q. 2015. When did the process start of you 2 reviewing documents, depositions, and medical 3 literature for purposes of writing your report?</p> <p>4 A. Right in November.</p> <p>5 Q. In terms of putting the literature 6 together, did that process start with Mr. Matthews 7 giving you a list of literature and you adding to it?</p> <p>8 A. They initially sent some papers, journal 9 manuscripts, that sort of thing. And then I also, 10 you know, did my own literature review and -- 11 literature review and search and put things together 12 myself as well, yes.</p> <p>13 Q. And I assume that with respect to 14 Exhibit 7, it's unlikely you'd be able to say today 15 which of these articles were given to you and which 16 you put on the list?</p> <p>17 A. Right. There's a combination of things in 18 there.</p> <p>19 Q. In terms of the notice of deposition, 20 which was marked as Exhibit 2, back to that, you have 21 brought your complete file in this case?</p> <p>22 A. Yes.</p> <p>23 Q. Is there anything you didn't bring?</p> <p>24 A. No.</p>
<p style="text-align: center;">Page 23</p> <p>1 A. Correct, a portion of those.</p> <p>2 Q. Right, 'cause right now we're talking 3 about the internal documents, we're not talking about 4 the literature?</p> <p>5 A. Correct, or -- yeah, literature, my 6 experience.</p> <p>7 Q. Right. So as to the literature, how did 8 literature get on this reliance list? In other 9 words, was literature given to you by Mr. Matthews 10 and then put on the list, or did you give him 11 literature, or was it a combination, or what was it? 12 This is an open-ended question.</p> <p>13 A. It was a combination. They gave me some 14 literature, but I also added a lot of literature to 15 that as well.</p> <p>16 Q. How long did the process take of putting 17 that literature together? And I guess let me strike 18 that question and ask a different one.</p> <p>19 When were you first contacted by 20 Mr. Matthews to be an expert witness on behalf of 21 plaintiffs against Ethicon?</p> <p>22 A. I think it was back in either late October 23 or early November of 2014 -- not 2014, I'm sorry, 24 2015.</p>	<p style="text-align: center;">Page 25</p> <p>1 Q. One of the categories, Number 31, asks for 2 communication between you and counsel for the 3 plaintiff, to the extent that those communications 4 either relate to your compensation, identify facts or 5 data provided to you that you used, and assumptions 6 that you were asked to make. Is there any such 7 correspondence or documentation?</p> <p>8 A. No, I don't believe so.</p> <p>9 Q. Has all of your communication with 10 Mr. Matthews and others in his firm been on the 11 phone?</p> <p>12 A. Yes. And they sent some e-mails for 13 Dropbox files to obtain these files electronically.</p> <p>14 MS. MAIMBOURG: Off the record. 15 (Discussion off the record.)</p> <p>16 Q. (By Ms. Maimbourg) All right. From 17 reading your report and looking at your CV, it's my 18 understanding that your current practice is at the 19 Atlanta Center For Laparoscopic Urogynecology and the 20 Beverly Hills Sunset Surgery Center; is that true?</p> <p>21 A. Yes.</p> <p>22 Q. Does that also go by the name of the 23 International Laparoscopic Center, or words to that 24 effect?</p>

7 (Pages 22 to 25)

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<p style="text-align: center;">Page 26</p> <p>1 A. We've had kind of several names throughout 2 the years. It also goes under the name, yes, 3 International Urogynecology Associates, as well 4 Miklos & Moore Urogynecology.</p> <p>5 Q. Is there some reason for all those names?</p> <p>6 A. As we've expanded our practice to a 7 satellite office in Beverly Hills, and now in Dubai, 8 we've just kind of added satellite office names, and 9 then changed the name to International. And then 10 finally figured out we should just call it Miklos & 11 Moore Urogynecology.</p> <p>12 Q. I know for the Atlanta Center, you are the 13 director of advanced pelvic surgery or the 14 co-director of urogynecology. How many people or 15 physicians are in the group?</p> <p>16 A. There's just my partner, myself as 17 partners. And we have an associate gynecologist that 18 has her own practice. She's a gynecologist, not a 19 urogynecologist.</p> <p>20 Q. Does she work at the Atlanta Center For 21 Laparoscopic Urogynecology?</p> <p>22 A. She does. She has her own practice there, 23 her own separate business, but she is -- we're 24 involved with that business, so she works with us,</p>	<p style="text-align: center;">Page 28</p> <p>1 trials.</p> <p>2 Q. What are you currently doing a research 3 trial on?</p> <p>4 A. We've got several trials that we're doing 5 right now. One is a medication to -- it's an FDA 6 trial for medication to treat fibroids, and try to 7 shrink fibroids without going to surgery. Another is 8 an interstitial cystitis medication. Another is an 9 overactive bladder medication. And I think that's 10 the current trials that are being run right now.</p> <p>11 Q. Have you --</p> <p>12 A. One more. We're also doing a trial with 13 radiofrequency to treat urinary incontinence.</p> <p>14 Q. Would that be considered a device?</p> <p>15 A. Yes.</p> <p>16 Q. Are those clinical trials listed on your 17 CV?</p> <p>18 A. They should be. If not, we can get you 19 the --</p> <p>20 Q. And how long has Atlanta Medical Research, 21 Inc. been in existence?</p> <p>22 A. Since I joined the practice, so at least 23 2001. Not sure when it was actually started by our 24 partner before that.</p>
<p style="text-align: center;">Page 27</p> <p>1 yes.</p> <p>2 Q. But she's not your employee?</p> <p>3 A. Not -- she's an employee of her own 4 business.</p> <p>5 Q. And so when you say you're the co-director 6 of urogynecology at the Atlanta Center, that's you 7 and Dr. Miklos who are the only partners are the 8 co-directors?</p> <p>9 A. Yes.</p> <p>10 Q. And in terms of the Beverly Hills Sunset 11 Surgery Center, your title there is chief of the 12 division of female pelvic medicine and reconstructive 13 surgery?</p> <p>14 A. Yes.</p> <p>15 Q. Is that just you and Dr. Miklos there?</p> <p>16 A. Currently, yes.</p> <p>17 Q. One other thing on your CV or your report 18 that caught my eye was, you list Atlanta Medical 19 Research, Inc., where you are the co-director and 20 managing partner; is that true?</p> <p>21 A. Yes.</p> <p>22 Q. What is that entity?</p> <p>23 A. That's a business that we run out of our 24 practice and office as well here that we do research</p>	<p style="text-align: center;">Page 29</p> <p>1 Q. Besides that research that you do and your 2 practice, can you identify other significant 3 professional activities that you are involved?</p> <p>4 A. Besides just my -- I've got roles in the 5 International Urogynecology Association, as far as 6 being on committees, and a couple different 7 committees. The Laparoscopic Special Interest Group, 8 which takes some work to get involved -- to be ready 9 for the meeting and present and getting some 10 different things ready for training and that sort of 11 thing for the -- that special interest group.</p> <p>12 I'm also involved -- I was on the public 13 relations committee as well for the International 14 Urogynecology Association, which again, fair amount 15 of work in getting things together for them. And now 16 I'm on the -- I'm on the board for the Foundation of 17 the International Urogynecology Association, which is 18 a foundation that supports the work that they do in 19 Ghana.</p> <p>20 Q. So you practice medicine in maybe three 21 locations?</p> <p>22 A. Yes.</p> <p>23 Q. That would be Atlanta, Beverly Hills, and 24 Dubai?</p>

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<p>1 A. Dubai is just starting, yes.</p> <p>2 Q. And you do research and you're pretty</p> <p>3 involved with IUGA?</p> <p>4 A. Yes, and I've been involved with other</p> <p>5 organizations throughout the years, but primarily</p> <p>6 involved with IUGA right now.</p> <p>7 Q. How recent is the Dubai part of your</p> <p>8 business?</p> <p>9 A. We just did the grand opening, I think</p> <p>10 about late last -- no, I think it was earlier this</p> <p>11 year. And then our first patients are actually going</p> <p>12 to be this summer?</p> <p>13 Q. The summer of 2016?</p> <p>14 A. Yes.</p> <p>15 Q. What was your motivation to go to Dubai?</p> <p>16 A. They requested us to come there. One of</p> <p>17 our associates from our office out in Los Angeles has</p> <p>18 been working there for several years. And they did</p> <p>19 not have a urogynecology division at the hospital</p> <p>20 where he was working. So he was kind of the one that</p> <p>21 spearheaded the movement to see -- to get us invited</p> <p>22 to come there as visiting surgeons.</p> <p>23 Q. This is a colleague of yours in Beverly</p> <p>24 Hills?</p>	<p>1 see patients as part of that. But I mean, if you</p> <p>2 wanted to say -- I would say 75 percent of my time is</p> <p>3 patient, clinically oriented.</p> <p>4 Q. And what percentage of that is in Atlanta</p> <p>5 versus Beverly Hills?</p> <p>6 A. We're in Beverly Hills for about a week</p> <p>7 every four to six weeks.</p> <p>8 Q. And you actually use the term "we," and I</p> <p>9 was sort of talking about you. So do you travel with</p> <p>10 Dr. Miklos?</p> <p>11 A. Yes, typically, we cover the Beverly Hills</p> <p>12 office together, yes.</p> <p>13 Q. So when you're in Atlanta, he's in</p> <p>14 Atlanta. When you're in Beverly Hills, he's in</p> <p>15 Beverly Hills, unless you're at meetings or something</p> <p>16 like that?</p> <p>17 A. Yes.</p> <p>18 Q. How long have you been a partner with him?</p> <p>19 A. Since 2001.</p> <p>20 Q. In terms of the surgery that you do, if</p> <p>21 you can tell me what percentage is for treatment of</p> <p>22 SUI, stress urinary incontinence?</p> <p>23 A. Typically, about 80 percent of our patient</p> <p>24 population is urogynecology in nature, which is</p>
<p style="text-align: center;">Page 31</p> <p>1 A. Yes, David Matlock.</p> <p>2 Q. Does he work with you at the surgery</p> <p>3 center there?</p> <p>4 A. No, he owns the surgery center. So I</p> <p>5 mean, we work with him in that regards, but no, we</p> <p>6 don't do surgeries with him, we don't share patients</p> <p>7 with him, per se.</p> <p>8 Q. Do you expect that you'll be doing any</p> <p>9 surgery on women who have had gentle mutilation</p> <p>10 surgery -- or not -- I guess it's not considered</p> <p>11 surgery -- genital mutilation?</p> <p>12 A. I don't know. There's a possibility of</p> <p>13 that, yes.</p> <p>14 Q. Taking all of these professional</p> <p>15 activities into account, can you tell me, if you can</p> <p>16 estimate the percentage involved in patient care</p> <p>17 including surgery?</p> <p>18 A. I would say 80 percent of my time</p> <p>19 is -- and you want to separate out Atlanta research?</p> <p>20 Q. Right, 'cause that's not really patient</p> <p>21 care, unless you define it as such?</p> <p>22 A. Yeah. I mean, it -- to me, it almost is,</p> <p>23 because we -- you know, these are -- these are</p> <p>24 typically, you know, patient clinical trials. So we</p>	<p style="text-align: center;">Page 33</p> <p>1 prolapse incontinence. A majority of those patients</p> <p>2 have incontinence. So I would say 60 to 75 percent</p> <p>3 of those patients that have prolapse also have</p> <p>4 incontinence issues that are treated surgically.</p> <p>5 Q. So it's a significant part of your</p> <p>6 practice?</p> <p>7 A. Yes.</p> <p>8 Q. And you do, I would assume by virtue of</p> <p>9 your last answer, do treat prolapse in your women</p> <p>10 patients?</p> <p>11 A. Yes.</p> <p>12 Q. And you do cosmetic surgery?</p> <p>13 A. Yes.</p> <p>14 Q. And one of those cosmetic surgeries is</p> <p>15 labiaplasty?</p> <p>16 A. Yes.</p> <p>17 Q. How big of a part of your practice is</p> <p>18 that?</p> <p>19 A. The cosmetic side of things, which would</p> <p>20 include both what we term kind of functional surgery</p> <p>21 or reconstruction or rejuvenation for sexual function</p> <p>22 after childbirth trauma, as well as labiaplasty or</p> <p>23 cosmetic side of things, that's kind of considered</p> <p>24 both elective and cosmetic. That's about 20 percent</p>

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<p>1 of the practice. Twenty percent of my surgical 2 practice.</p> <p>3 Q. So if someone wants to have their vagina 4 tightened up so that they have better sex, you 5 would -- you consider that cosmetic surgery?</p> <p>6 A. Well, I don't consider it cosmetic 7 surgery, but insurance companies consider it cosmetic 8 surgery.</p> <p>9 Q. And I know -- how many times have you 10 recreated a hymen?</p> <p>11 A. Probably maybe 40.</p> <p>12 Q. Is there any medical reason to recreate a 13 hymen?</p> <p>14 A. There's social reasons to do that, and 15 it's a patient choice reason to do it. And one would 16 say from their aspect, from the woman's aspect, that 17 there may be a medical need for it to prevent them 18 from being harmed physically for not having an intact 19 hymen.</p> <p>20 Q. Who would be harmed physically? Do you 21 mean people who are perhaps of a certain faith?</p> <p>22 A. It's not necessarily a faith or religion, 23 it's a cultural issue that women in certain cultures 24 and certain countries, if they don't have an intact</p>	<p>1 control and the power back to have the choice of who 2 was going to kind of take that from her per se, so 3 that was the one other one.</p> <p>4 Q. Is there any other surgery that you do 5 that takes up any significant part of your time, you 6 know, we've talked about SUI, prolapse, cosmetic. Is 7 there any other category I might have missed?</p> <p>8 A. No, I don't believe so.</p> <p>9 Q. In terms of surgery to correct or treat 10 stress urinary incontinence, what procedures did you 11 learn in your residency and fellowship? And that 12 would have spanned 1994 through the year 2000?</p> <p>13 A. I learned the Burch procedure, pubovaginal 14 sling, midurethral slings, which would have included 15 at that point in time just the retropubic 16 tension-free vaginal tape slings -- the retropubic 17 midurethral slings, including the -- at that point in 18 time, it would have been the TVT, the tension-free 19 vaginal tape sling, as well as injectable agents. 20 Periurethral bulking agents.</p> <p>21 Q. Did you learn the MMK?</p> <p>22 A. No, at that point in time, it was really 23 kind of going out of vogue, secondary to 24 the -- increased risk of pubic osteomyelitis that was</p>
<p style="text-align: center;">Page 35</p> <p>1 hymen or bleed per se on their wedding night, that 2 they can be harmed physically, mentally, thrown out 3 of their family, abused in that fashion, so yes.</p> <p>4 Q. Are all of the hymens that you've 5 recreated been under those circumstances?</p> <p>6 A. I would say 99 percent.</p> <p>7 Q. And then the 1 percent actually got on TV, 8 right?</p> <p>9 A. Yes.</p> <p>10 Q. Has there been more than one hymen that 11 you've created just for sexual pleasure -- or not 12 sexual pleasure, for recreating a honeymoon?</p> <p>13 A. There may have been one other woman who 14 was -- she was coming in for reconstruction 15 vaginally. She had been raped by her husband or 16 partner the day she came home from delivering her 17 baby, so she got completely traumatized. And the 18 vagina completely torn open and ripped open and took 19 her many years to kind of get over that.</p> <p>20 And then ultimately with her 21 reconstruction, had met a new partner and was getting 22 married and wanted her hymen reconstructed at the 23 time of that procedure to basically give her the 24 control -- these are her words -- give her the</p>	<p style="text-align: center;">Page 37</p> <p>1 occurring after the MMK, so I learned the Burch 2 procedure.</p> <p>3 Q. Did you learn it abdominally and 4 laparoscopically?</p> <p>5 A. I learned it abdominally in residency and 6 laparoscopically in fellowship, yes.</p> <p>7 Q. And you did say you were trained to 8 implant both the pubovaginal sling and the 9 polypropylene midurethral slings?</p> <p>10 A. Yes.</p> <p>11 Q. Where did you do your fellowship?</p> <p>12 A. I did my fellowship at Northside Hospital 13 here in Atlanta.</p> <p>14 Q. When you completed your training in 2000 15 and up through the present, so that would be the last 16 15 plus years, have you continued to do all of those 17 procedures?</p> <p>18 A. I don't -- I haven't done a pubovaginal 19 sling in many years, but all the other procedures, 20 yes.</p> <p>21 Q. How frequently do you do a Burch?</p> <p>22 A. Now it seems to be mostly our primary 23 procedure to treat stress urinary incontinence. So I 24 do probably two a week.</p>

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<p>1 Q. Do you do them laparoscopically? 2 A. Yes. 3 Q. Only? 4 A. Yes. 5 Q. And are you still implanting midurethral 6 slings? 7 A. Yes. 8 Q. What is the midurethral sling that you 9 currently implant? 10 A. I've been utilizing the RetroArc, which is 11 the Sparc procedure that's done from below once they 12 release that. And was utilizing the AMS Mini-Arc, 13 Mini sling. Those are no longer available to me, so 14 I will have to take a look and see what products that 15 I will use in the future for midurethral slings. 16 Q. So just so the record is clear, the Sparc 17 is a midurethral sling, was manufactured by AMS and 18 it's a retropubic? 19 A. Yes. 20 Q. And the Mini-Arc is a single incision 21 sling that was manufactured by AMS? 22 A. Yes. 23 Q. And your reference to not having those 24 available is a reference to the fact that AMS has</p>	<p>1 A. Because I always liked the device sling 2 technology of the Sparc procedure. I wasn't 3 comfortable doing it from above, was more comfortable 4 doing the procedure from below. However, I liked the 5 fact that in their sling and mesh, they had what was 6 called a tensioning suture in place, so that as the 7 plastic sheath was taken off over the mesh, the mesh 8 itself wouldn't stretch out or get what's called a 9 bounce back effect. 10 So for many years, I was kind of on them 11 to get us a procedure that we could do from below 12 with the Sparc tape to benefit from that tensioning 13 sling. 14 Q. And when you say below, you mean making an 15 incision in the vagina and then going out the 16 abdomen? 17 A. Correct. 18 Q. And the Sparc is -- goes in the abdomen 19 and out the vagina? 20 A. Correct. It's a -- what would be called a 21 top-down versus a bottom-up approach. 22 Q. And what is TVT? 23 A. It's a bottom-up approach. 24 Q. You did not stop using TVT retropubic</p>
<p style="text-align: center;">Page 39</p> <p>1 decided to get out of that business? 2 A. Yes. 3 Q. Are those off the shelves? 4 A. They are at our hospital, yes. 5 Q. Just because you've run out? 6 A. No, because I think once they called a 7 halt to their business, I think March 31st, the 8 hospital took them off the shelves. 9 Q. There was not a concern of safety or 10 efficacy of those products when that company decided 11 to stop marketing them, was there? 12 MS. MARIGLIANO: Object to the form. 13 THE WITNESS: No, not that I believe. 14 Q. (By Ms. Maimbourg) And if you had them 15 today, you would be using them? 16 A. Yes. 17 Q. At some point in time, you did use the TVT 18 retropubic; is that true? 19 A. Yes. 20 Q. When was that? 21 A. That would have been probably up until 22 about two years ago, when the RetroArc became 23 available. 24 Q. Why did you make the change?</p>	<p style="text-align: center;">Page 41</p> <p>1 because of any concern about safety or efficacy, did 2 you? 3 A. I did not. I had to modify the procedure, 4 though, so to eliminate kind of some of the issues I 5 was having with when I was pulling the sheath off, 6 and getting that bounce-back effect that was 7 tensioning the sling too tight right off the bat. So 8 I'd have to modify my technique in order to overcome 9 that issue. 10 Q. And that issue that you're describing with 11 the sheath technology that -- from -- if I'm 12 understanding your answer, was a concern from 13 tensioning. And therefore, you wouldn't want to 14 tension it too much because then the woman might have 15 retention? 16 A. Retention, urinary obstructive type 17 symptoms, urgency, frequency, increased risks of 18 basically contracture of the slings and the pore 19 sizes that ultimately can lead to roping and 20 contraction and those sort of phenomenons that we've 21 seen. 22 Q. We'll hopefully get to all of that. 23 (Exhibit 8 was marked for 24 identification.)</p>

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<p style="text-align: right;">Page 42</p> <p>1 Q. (By Ms. Maimbourg) Doctor, I'm handing 2 you Exhibit 8, if you'll just take a look at it. Let 3 me know when you're done. 4 A. Uh-huh. 5 Q. All right. This document is a chart, and 6 it's labeled Potential Risks of Non-Mesh SUI Surgery 7 at the top, right? 8 A. Yes. 9 Q. And among -- I mean, this would include 10 Burch procedures, pubovaginal sling procedures, and I 11 suppose the MMK, if someone wanted to do an MMK, 12 right? 13 A. Yes. 14 Q. Do you agree that this list contains or 15 includes potential risks of non-mesh SUI surgery? 16 A. Yes. 17 Q. And if any of these risks actually 18 developed, do you agree the effect on the patient 19 could be temporary or chronic? 20 MS. MARIGLIANO: Object to the form. 21 THE WITNESS: Yes. 22 Q. (By Ms. Maimbourg) And if these risks 23 developed, do you agree that the effect on the 24 patient could be mild, moderate, or severe?</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. And that was manufactured by AMS? 2 A. Yes. 3 Q. Were you a preceptor for AMS? 4 A. Yes. 5 Q. And that means you were teaching other 6 physicians how to implant? 7 A. Yes. 8 Q. Were you acting in any other consultancy 9 capacity with AMS? 10 A. Yes, I was a consult -- I mean, I was a 11 consultant, I was a speaker for them, I was a 12 preceptor, I did research trials with them. 13 Q. Did you do any research trials on pelvic 14 mesh devices? 15 A. Yes. 16 Q. Which ones? 17 A. Monarc, Mini-Arc, Apogee, Perigee and 18 Elevate. 19 Q. Is AMS -- well, let's say, was AMS a 20 competitor of Ethicon for slings and prolapse 21 devices? 22 A. Yes. 23 Q. Why did you stop implanting the Monarc? 24 A. Because I felt the risks outweighed the</p>
<p style="text-align: right;">Page 43</p> <p>1 A. Yes. 2 Q. In order to do non-mesh SUI surgery, do 3 you believe that doctors should be aware of these 4 risks? 5 A. Yes. 6 Q. As to slings, and specifically I think you 7 said in your report that you had implanted -- on page 8 4, you said you've implanted more than a thousand. 9 You can look at your report if that helps remind you. 10 A. Yes. 11 Q. Does this include the period of your 12 residency and fellowship? 13 A. I mean, that's a small portion of my 14 training, so I didn't implant any mesh slings during 15 my residency. It would have been during my 16 fellowship. So the majority of those were after my 17 training. 18 Q. And then on page 5, you say, from 2003 to 19 2008, somewhere in the middle, you say that you used 20 transobturator slings with an outside-in approach, 21 correct? 22 A. Yes, correct. 23 Q. And was that the Monarc? 24 A. Yes.</p>	<p style="text-align: right;">Page 45</p> <p>1 benefit of a transobturator approach and having mesh 2 in the groins, when there were alternatives that were 3 available at that point in time to avoid that. 4 Q. Is that when you started using the 5 retropubic sling manufactured by AMS, or is that when 6 you went to TVT? 7 A. No, I had always used the retropubic sling 8 from AMS as a procedure that typically would be used 9 in patients that have failed other procedures, or had 10 severe ISD, which is intrinsic sphincter deficiency 11 or basically a urethra that just doesn't work very 12 well. The retropubic slings had always been shown to 13 be more efficacious in those type of procedures, 14 which was probably overall only about 5 percent of 15 the incontinence patients that I dealt with. 16 And again, as I stated earlier, AMS didn't 17 have a bottom-up type of an approach with their mesh, 18 and I was not comfortable with, nor felt that we 19 could get as good results from the top-down, 20 therefore, I utilized the TVT sling at that time. I 21 think I also utilized the Caldera sling, which is a 22 little bit stiffer in nature, and I liked the fact 23 that that particular sling, again, did not stretch or 24 become tensioned during the sheath removal.</p>

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<p style="text-align: right;">Page 46</p> <p>1 Q. And that again was something that impacted 2 efficacy, not safety? 3 MS. MARIGLIANO: Object to the form. 4 THE WITNESS: I mean, I would say that it 5 impacted efficacy, but safety in the fact that 6 ultimately safety -- not during the procedure 7 itself, but ultimately, could increase risk of 8 complications later. 9 Q. (By Ms. Maimbourg) I thought -- my 10 understanding was, is that this tensioning issue had 11 to do with retention or overactive bladder symptoms 12 or things like that after the procedure. Did I 13 misunderstand you? 14 MS. MARIGLIANO: Object to the form. Go 15 ahead. 16 THE WITNESS: No, you didn't misunderstand 17 me, but I guess, you know, when we talk about -- 18 if you talk about safety of the procedure during 19 the procedure itself, then, no, I don't think it 20 impacted that. 21 Q. (By Ms. Maimbourg) I actually wasn't 22 talking about during the procedure, I was talking 23 about -- well, strike it. It's not worth it to go 24 into, given the limited amount of time we have.</p>	<p style="text-align: right;">Page 48</p> <p>1 procedure during that time frame. 2 However, during that time frame, I was 3 still also utilizing retropubic slings. Once we had 4 access to the Mini-Arc, at that point in time, that's 5 when I stopped utilizing the Monarc. And then 6 Mini-Arc kind of took over Monarc's place, in the 7 same amount of time frame, the retropubic sling was 8 still being utilized in my hands, 5 to 10 percent of 9 the time. 10 Q. If a patient came in tomorrow, and you saw 11 her for surgical treatment of SUI, what sling devices 12 would you be able to offer her? 13 A. I would be able to offer her a retropubic 14 sling approach by any manufacturer that still has one 15 on the market, as well as laparoscopic Burch 16 procedure, or a Mini sling that any company still has 17 on the market. 18 Q. Are you doing more Burch procedures than 19 slings now? 20 A. Yes. 21 Q. And for how long has that been? 22 A. That has been probably over the 23 last -- it's been slowly occurring over the last two 24 years.</p>
<p style="text-align: right;">Page 47</p> <p>1 Have you, to this date, ever implanted an 2 Abbrevio? 3 A. No. 4 Q. Have you implanted an Exact? 5 A. Yes. 6 Q. When? 7 A. Again, that was the last product I think 8 that was available from kind of the TTVT retropubic 9 Align, before I started using the RetroArc. 10 Q. So if I get -- my understanding is from 11 2003 to 2008, you used the Monarc sling. You then 12 felt the risks outweighed the benefits, so you 13 stopped doing that, and you went to retropubic 14 slings, either the TTVT, the Caldera, or the Exact. 15 And then at some point in time, you went to this AMS 16 product because they developed a bottom-up. Is that 17 true? 18 A. No. 19 Q. Okay. What's wrong with that scenario? 20 A. So throughout that time frame that I was 21 utilizing Monarc, I was also utilizing a retropubic 22 sling for more complex patients, failures, ISD, 23 et cetera, which is probably only about 5 percent of 24 my incontinent population. Monarc was the primary</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Have you ever been a consultant for 2 Ethicon? 3 A. For a very short period of time, right 4 when I was done with fellowship, I think in the time 5 frame of 2001, 2002 time frame. 6 Q. And you acted at that time as a preceptor 7 for the TTVT retropubic? 8 A. My partner was one of the initial four or 9 five to kind of bring TTVT slings to this country, so 10 he was their primary preceptor. I helped him, 11 assisted him, because again, I was young and new to 12 the practice. And then I was involved with a couple 13 labs that I instructed at, cadaver labs for Ethicon. 14 So I wouldn't say -- I was never a primary preceptor 15 that they sent people to. They would send them to my 16 partner. 17 Q. But if Ethicon's records listed you as 18 being a preceptor at two different cadaver labs, and 19 at an advanced training session, you would have no 20 reason to doubt that, if it was in the 2002 time 21 frame? 22 A. No, I wouldn't have a reason to doubt it. 23 (Exhibit 9 was marked for 24 identification.)</p>

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<p style="text-align: center;">Page 50</p> <p>1 Q. (By Ms. Maimbourg) Doctor, I've handed 2 you what has been marked as Exhibit 9, and it's 3 entitled Potential Risks of Non-Mesh and Mesh SUI 4 Surgeries. Just take a look at it and let me know 5 when you're done.</p> <p>6 A. Okay.</p> <p>7 Q. So just with respect to the column on the 8 right that's entitled Mesh, do you agree that the 9 right -- that this column lists the risks of mesh 10 surgeries?</p> <p>11 MS. MARIGLIANO: Object to the form.</p> <p>12 THE WITNESS: Yes, I do.</p> <p>13 Q. (By Ms. Maimbourg) And do you agree that 14 any -- if any of these risks develop, that the effect 15 on the patient could be temporary or chronic?</p> <p>16 A. Yes.</p> <p>17 Q. And do you agree that if any of these 18 risks developed, the effect on the patient could be 19 mild, moderate, or severe?</p> <p>20 A. Yes, I do. Relative risks aren't listed 21 certainly here on this chart, so that would be one 22 issue that I'd have with the chart, just listing out 23 complications without putting down actually the 24 relative risks of the different complications.</p>	<p style="text-align: center;">Page 52</p> <p>1 indications for removal, and then -- 2 (Exhibit 12 was marked for 3 identification.)</p> <p>4 Q. (By Ms. Maimbourg) And then Exhibit 12, 5 you also brought this?</p> <p>6 A. Exhibit 12 is kind of the main study that 7 actually classifies every patient that came in with a 8 mesh complication, utilizing the IUGA/ICS 9 classification of synthetic mesh complications of all 10 of these patients. So the first one is just 11 classifying the different complications via the 12 official IUGA/ICS classification system.</p> <p>13 Q. When you said the first one, you were 14 actually holding Exhibit 12?</p> <p>15 A. Exhibit 12, yes.</p> <p>16 Q. Right. So are all of these -- and I 17 apologize, 'cause I didn't have those first two 18 abstracts before today. Is the data in 10 and 11 19 also in 12? No, is that -- partially?</p> <p>20 A. Yes, I would say all of the patients -- 21 it's the same patient population from three centers, 22 our center, Emory University, and Cleveland Clinic, 23 Florida. All the patients, all the mesh 24 complications are the same in each of these papers.</p>
<p style="text-align: center;">Page 51</p> <p>1 Q. Okay. If we have time, we'll go back over 2 that. You know what? Before we move on, I do want 3 to mark three articles that you brought with you 4 today, and I'm just going to have you identify them 5 for the record. What is Exhibit 10, Doctor?</p> <p>6 (Exhibit 10 was marked for 7 identification.)</p> <p>8 THE WITNESS: This is an abstract that we 9 presented at the American Urogynecology Society 10 meeting in 2014 on Indication of Surgical 11 Treatment of Midurethral Sling Complications, a 12 Multicenter Study.</p> <p>13 Q. (By Ms. Maimbourg) Is that -- was that 14 mentioned in your report?</p> <p>15 A. Yes.</p> <p>16 Q. And then Exhibit 11 is also the same data 17 presented at a different time?</p> <p>18 (Exhibit 11 was marked for 19 identification.)</p> <p>20 THE WITNESS: No, it's basically just a 21 sub-analysis of the data that this first one 22 that we talked about, Exhibit 10, is just about 23 slings. This one is talking about specifically 24 either slings or pelvic organ prolapse</p>	<p style="text-align: center;">Page 53</p> <p>1 However, 12, which is really the main paper -- 10 and 2 11, Exhibit 10 and 11 are sub-analysis of this data.</p> <p>3 Q. That helps a lot. Keep those there, 4 because I will ask some questions about 12. Just 5 stick them up there. All right.</p> <p>6 (Exhibit 13 was marked for 7 identification.)</p> <p>8 Q. (By Ms. Maimbourg) I'm going to mark as 9 Exhibit 13 --</p> <p>10 (Discussion off the record.)</p> <p>11 Q. (By Ms. Maimbourg) Doctor, this was 12 printed on April 12th of 2016, if you could see that 13 date on the top left of this document. Could you 14 identify what this is?</p> <p>15 A. This looks like a page from one of our 16 websites.</p> <p>17 Q. And actually, it's the International 18 Center For Laparoscopic Urogynecology, right?</p> <p>19 A. Yes.</p> <p>20 Q. And that is one of the names of your 21 practice?</p> <p>22 A. Yes.</p> <p>23 Q. So in this section on TVT sling 24 complications, the first sentence says, Although the</p>

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<p>1 TVT sling is considered the standard of care, 2 complications can still occur. That's what it says, 3 right?</p> <p>4 A. Yes.</p> <p>5 Q. And are you referring to any particular 6 type of sling in that sentence that you say TVT?</p> <p>7 A. I mean, we're using it more generically as 8 a retropubic midurethral sling.</p> <p>9 Q. Would a standard -- strike that.</p> <p>10 The second sentence says, It is very 11 important to note that it may not be the mesh itself 12 or the procedure that is the cause of the 13 complication. It may be how the mesh is placed or 14 how the body heals around the mesh that may be part 15 of the underlying cause. That's on the -- your 16 website page today, right?</p> <p>17 A. This is actually -- I guess it's still 18 available. I mean, this is an older version of our 19 website, but if you just printed it April 12th, I 20 guess it's still out there and available, so --</p> <p>21 Q. Well, is this still your opinion today?</p> <p>22 A. Yes, I think we've updated it on our new 23 website as well to say as well, that it certainly 24 depends not only on those factors, but also the</p>	<p>1 section of the website.</p> <p>2 Q. Which website?</p> <p>3 A. Miklos & Moore.</p> <p>4 Q. Since I don't have that before me right 5 now, what does it say?</p> <p>6 MS. MARIGLIANO: Object to the form. Go 7 ahead.</p> <p>8 THE WITNESS: It says while -- and again, 9 I can't quote it. We'd have to take a look at 10 it to quote the exact statement, but the gist of 11 the statement says that -- it describes what a 12 transobturator tape sling is, it describes and 13 states that they still are available on the 14 market today, and surgeons utilize them. 15 However, we, meaning my partner and myself, 16 don't perform the procedures any longer. We 17 don't feel that they should be performed. We 18 feel that the risks outweigh the benefit for the 19 procedure, and that there are safer alternatives 20 that are just as efficacious.</p> <p>21 Q. (By Ms. Maimbourg) How long has that 22 statement been on your website?</p> <p>23 A. I don't know if it was in this version or 24 not. You'd have to take a look at the TOT sling</p>
<p style="text-align: center;">Page 55</p> <p>1 particular make-up of the mesh itself, meaning, you 2 know, the type of mesh that it is, and certainly 3 that's a factor in addition to these factors right 4 here.</p> <p>5 Q. What website would I look to, if I wanted 6 to find that updated information?</p> <p>7 A. Miklos & Moore Urogynecology.</p> <p>8 Q. Does --</p> <p>9 A. And it actually says that right here, too. 10 Of course, the qualities and properties of a 11 particular brand or type of mesh used may also play 12 role in complications.</p> <p>13 Q. All right. So what you just mentioned 14 that's on your website, the Miklos & Moore, is also 15 here?</p> <p>16 A. Yes.</p> <p>17 Q. On this website, the International Center, 18 or on Miklos & Moore, or any of your other websites, 19 do you have any statement cautioning patients against 20 having a sling that is implanted via an obturator 21 approach?</p> <p>22 A. Yes.</p> <p>23 Q. Where does it say that?</p> <p>24 A. It would be underneath the TOT sling</p>	<p style="text-align: center;">Page 57</p> <p>1 portion of that website, but this -- our new website 2 has been in the makings for at least a year.</p> <p>3 Q. In terms of mesh removal, which you 4 describe on page 6 of your report, you have a couple 5 different numbers there, and I just wanted to clarify 6 in my own mind.</p> <p>7 MS. MARIGLIANO: I'm sorry, what page?</p> <p>8 MS. MAIMBOURG: Six.</p> <p>9 Q. (By Ms. Maimbourg) Are you there?</p> <p>10 A. Yes.</p> <p>11 Q. So if you go down to the bottom, it says, 12 My partner and I have explanted more than 700 mesh 13 devices, with more than 500 since 2010?</p> <p>14 A. Uh-huh.</p> <p>15 Q. And then up above, on the very first part, 16 you said, More than 500 pieces in the last four 17 years. And since four years would actually be 2011 18 through 2015, I just wanted to clarify what the 19 accurate numbers are.</p> <p>20 A. I would say the accurate numbers are this 21 down here below, because we know -- you know, 22 basically, we've got very good numbers based from the 23 study from the years 2011 to 2013, in which there was 24 500 pieces of meshes explanted in this trial. We did</p>

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<p>1 75 percent of those from the three centers, so that 2 was over 300, we've explanted in the last two years. 3 Approximately about a hundred to 120 each year. And 4 so then, prior to 2010, from 2002 through 2010, you 5 know, there was least 200. I don't have those exact 6 numbers.</p> <p>7 Q. Of the ones that you've removed, you list 8 here that they've included Gynecare Prolift, Prolift 9 Plus M, Prosimma, TTV retropubic, TTV-O, and TTV-Secur 10 slings. I just want to make sure that you are not 11 saying the only mesh devices you've removed are those 12 products; is that true?</p> <p>13 A. That is true.</p> <p>14 Q. So you've just listed the Ethicon 15 products, but you've also removed products of other 16 manufacturers, true?</p> <p>17 A. Yes.</p> <p>18 MS. MARIGLIANO: Can we take a break, if 19 you're at a good stopping point?</p> <p>20 MS. MAIMBOURG: Sure. Yeah, let's take a 21 break. We've been going about an hour.</p> <p>22 (A recess was taken.)</p> <p>23 Q. (By Ms. Maimbourg) Doctor, we're back on 24 the record. I've asked you to look at your</p>	<p>1 Research, Inc.? 2 A. If it's available, yes. 3 Q. Do you believe it's available? 4 A. I don't know how many numbers of patients 5 that we actually have identified inside-out versus 6 outside-in.</p> <p>7 Q. In this article, you do not draw any 8 conclusions about pain being worse in the patients 9 with TOT inside-out compared to any other sling, do 10 you?</p> <p>11 A. No, we do not.</p> <p>12 Q. You also do not reach any conclusion to a 13 reasonable degree of certainty as to how the mesh was 14 causing pain, correct?</p> <p>15 A. In this particular study?</p> <p>16 Q. Yes.</p> <p>17 A. No.</p> <p>18 Q. In terms of conflict of interest 19 information on the last page, you say, none, right?</p> <p>20 A. Correct.</p> <p>21 Q. What is the purpose of the conflict of 22 interest provision in medical literature?</p> <p>23 A. To provide readers any potential bias that 24 may be involved.</p>
<p style="text-align: center;">Page 59</p> <p>1 Exhibit 12, which is the data you were referring to, 2 I think, in one of your last answers. So this 3 multi-center study, you already identified the three 4 institutions. You and your partner removed 373 5 slings, right?</p> <p>6 A. Yes.</p> <p>7 Q. And that's actually on page 2, you have 8 that data. And in this article, you do not breakdown 9 the type of slings by number, correct?</p> <p>10 A. Correct.</p> <p>11 Q. And I take that that you removed 12 retropubic single incision TOT inside-out and TOT 13 outside-in?</p> <p>14 A. Correct.</p> <p>15 Q. Do you have that data somewhere?</p> <p>16 A. It's actually in that -- one of those 17 abstracts that we talked about earlier, that's 18 specifically on mesh itself. I believe if you take a 19 break at it, what we've broken down --</p> <p>20 Q. Let me ask you this. Does it include a 21 breakdown of how many TOT slings were inside-out 22 versus outside-in in this study?</p> <p>23 A. It does not.</p> <p>24 Q. Is that data somewhere back at Atlanta</p>	<p style="text-align: center;">Page 61</p> <p>1 Q. Did you disclose here that you had 2 testified at least nine times for plaintiffs alleging 3 injuries from pelvic mesh, including slings?</p> <p>4 A. No.</p> <p>5 Q. Do you believe that a reader of this 6 article is entitled to know that you have been and 7 are continuing to be an expert for the plaintiffs 8 suing mesh manufacturers?</p> <p>9 MS. MARIGLIANO: Object to the form.</p> <p>10 THE WITNESS: It's not part of the 11 requirements as far as they bring you through a 12 very stringent bias -- or not bias, but 13 disclosure and conflict of interest form. And 14 it's not part of the disclosure process of this 15 journal, or any other journal that I know of 16 right now.</p> <p>17 Q. (By Ms. Maimbourg) So you don't believe 18 that it would be important, regardless of the process 19 you went through with this journal, you don't believe 20 it's important for readers of this article to know 21 that you're testifying on behalf of plaintiffs in 22 pelvic mesh litigation involving the very products 23 you are studying?</p> <p>24 MS. MARIGLIANO: Object to the form.</p>

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<p>1 THE WITNESS: I think for this particular 2 article, it's irrelevant. It's just a 3 classification of the numbers of patients that 4 came through that were -- that the types of 5 complications that they had, and the 6 classifications of them.</p> <p>7 Q. (By Ms. Maimbourg) You are a member of, I 8 think, 12 different societies -- I looked at your 9 CV -- including ACOG and AUGS; is that true?</p> <p>10 A. Yes.</p> <p>11 (Exhibit 14 was marked for 12 identification.)</p> <p>13 Q. (By Ms. Maimbourg) I'm handing you 14 Exhibit 14. Have you seen this before?</p> <p>15 A. No, I have not.</p> <p>16 Q. So this is the ACOG and AUGS Practice 17 Bulletin on Urinary Incontinence in Women, dated 18 November 5th, 2015. Did I say that correctly?</p> <p>19 A. Yes.</p> <p>20 MS. MARIGLIANO: What exhibit number? I'm 21 sorry.</p> <p>22 MS. MAIMBOURG: I'm sorry, it's 15 -- no, 23 14. Did I say it wrong? If I did, I apologize. 24 It's 14.</p>	<p>1 want to find it, E 74?</p> <p>2 A. Yeah, I'm on E 74.</p> <p>3 Q. The paragraph that begins, Although 4 controversy?</p> <p>5 A. Okay.</p> <p>6 Q. Are you there?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. I'm going to read it again: 9 Although controversy exists about the role of 10 synthetic mesh used in the vaginal repair of pelvic 11 organ prolapse -- and we're not here talking about 12 pelvic organ prolapse, right?</p> <p>13 A. Correct.</p> <p>14 Q. There are substantial safety and efficacy 15 data that support the role of synthetic mesh 16 midurethral slings as a primary surgical treatment 17 option for stress urinary incontinence in women. Do 18 you agree with that?</p> <p>19 MS. MARIGLIANO: Object to the form. Go 20 ahead.</p> <p>21 THE WITNESS: I agree that that's what 22 they state here, and I agree with the statement. 23 However, they don't break it down into which 24 particular slings and midurethral slings they're</p>
<p style="text-align: center;">Page 63</p> <p>1 Q. (By Ms. Maimbourg) Doctor, on page E 74, 2 I'm going to direct you to a couple statements -- or 3 actually, just probably one. You see the page 4 numbers?</p> <p>5 A. Yes.</p> <p>6 Q. Over on the right-hand column, it says, 7 There are substantial safety and efficacy data that 8 support the role of synthetic mesh midurethral slings 9 as a primary surgical treatment option for stress 10 urinary incontinence in women. Did I read that 11 correctly?</p> <p>12 MS. MARIGLIANO: I don't see where you're 13 at.</p> <p>14 MS. MAIMBOURG: Right here (indicating).</p> <p>15 Q. (By Ms. Maimbourg) So it's on the 16 right-hand column, last full paragraph.</p> <p>17 MS. MARIGLIANO: I'm going to object. You 18 didn't read the sentence in its entirety.</p> <p>19 MS. MAIMBOURG: I'm not done. I'm just 20 going one sentence at a time.</p> <p>21 MS. MARIGLIANO: I said you didn't read 22 the sentence in its entirety.</p> <p>23 Q. (By Ms. Maimbourg) Oh, I'll read the 24 sentence in the entirety. You're not even -- you</p>	<p style="text-align: center;">Page 65</p> <p>1 talking about. So for an overall global 2 statement, I think that it needs to specify 3 retropubic Mini slings, and exclude TOT slings, 4 in my opinion.</p> <p>5 Q. (By Ms. Maimbourg) The next sentence 6 says, For this reason, and to clarify uncertainty for 7 patients and practitioners, the American 8 Urogynecologic Society and the Society of 9 Urodynamics, Female Pelvic Medicine & Urogenital 10 Reconstruction published a position statement 11 recognizing polypropylene mesh midurethral slings as 12 the standard of care in the surgical treatment of 13 stress urinary incontinence.</p> <p>14 So my question to you first is, are you 15 aware that AUGS and SUFU published a position 16 statement recognizing polypropylene mesh midurethral 17 slings as the standard of care?</p> <p>18 A. Yes, as a standard of care.</p> <p>19 Q. And do you agree that midurethral slings 20 are considered the standard of care in treating SUI?</p> <p>21 MS. MARIGLIANO: Object to the form.</p> <p>22 THE WITNESS: No, I don't as a global 23 statement of midurethral slings. I believe, in 24 my opinion, they need to be subclassified into</p>

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<p style="text-align: center;">Page 66</p> <p>1 each particular type of midurethral sling.</p> <p>2 Q. (By Ms. Maimbourg) Have you ever</p> <p>3 communicated that to AUGS?</p> <p>4 A. Not officially, no.</p> <p>5 Q. Have you communicated it to ACOG?</p> <p>6 A. No.</p> <p>7 (Exhibit 15 was marked for</p> <p>8 identification.)</p> <p>9 Q. (By Ms. Maimbourg) I'm going to mark</p> <p>10 Exhibit 15. Doctor, this is entitled Position</p> <p>11 Statement on Mesh Midurethral Slings For Stress</p> <p>12 Urinary Incontinence, and it's an AUGS/SUFU</p> <p>13 statement, correct?</p> <p>14 A. Yes.</p> <p>15 Q. And due to the short time here, I'm just</p> <p>16 going to go to page 3, under the conclusion. Are you</p> <p>17 there?</p> <p>18 A. Yes.</p> <p>19 Q. And to give this context, this position</p> <p>20 statement is talking about all mesh midurethral</p> <p>21 slings, correct?</p> <p>22 A. This, again, gives a global classification</p> <p>23 of midurethral slings that they are including, yes.</p> <p>24 Q. And I understand that you think it should</p>	<p style="text-align: center;">Page 68</p> <p>1 that midurethral slings have been an important</p> <p>2 advancement in the treatment of stress urinary</p> <p>3 incontinence in women?</p> <p>4 MS. MARIGLIANO: Object to the form.</p> <p>5 THE WITNESS: I believe that some forms of</p> <p>6 midurethral slings have been an advancement in</p> <p>7 the treatment of women with urinary</p> <p>8 incontinence.</p> <p>9 (Exhibit 16 was marked for</p> <p>10 identification.)</p> <p>11 Q. (By Ms. Maimbourg) Doctor, I've placed</p> <p>12 before you Exhibit 16 entitled Frequently Asked</p> <p>13 Questions By Providers, Midurethral Slings For Stress</p> <p>14 Urinary Incontinence. And again, this is an AUGS and</p> <p>15 SUFU document. Have you seen this before?</p> <p>16 A. Yes.</p> <p>17 Q. And on the bottom of page 1, there's a</p> <p>18 question, Does the MUS mesh made of polypropylene</p> <p>19 degrade over time?</p> <p>20 I'd like you to read that to yourself,</p> <p>21 that answer. Do you agree with the answer?</p> <p>22 A. I don't agree or disagree. I mean, this</p> <p>23 is -- we can read it as such as they state this, but</p> <p>24 I really don't have an opinion on whether or not this</p>
<p style="text-align: center;">Page 67</p> <p>1 probably be broken out, but under the conclusion,</p> <p>2 does AUGS and SUFU say, last sentence, This</p> <p>3 procedure, meaning midurethral slings, is probably</p> <p>4 the most important advancement in the treatment of</p> <p>5 stress urinary incontinence in the last 50 years, and</p> <p>6 has the full support of our organizations which are</p> <p>7 dedicated to improving the lives of women with</p> <p>8 urinary incontinence. Does it say that?</p> <p>9 A. It does say that.</p> <p>10 Q. And do you agree with that?</p> <p>11 A. Again, I don't agree with the statement as</p> <p>12 stated, with a global kind of all catch one,</p> <p>13 midurethral slings, retropubic, TOT, single incision</p> <p>14 slings. I believe that it needs to be separated out,</p> <p>15 because I don't believe that the TOT slings have</p> <p>16 globally improved the lives of women with urinary</p> <p>17 incontinence. I believe it's caused too many</p> <p>18 complications, and there are safer alternatives.</p> <p>19 Q. And Abbrevio is a safer alternative, right?</p> <p>20 MS. MARIGLIANO: Object to the form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 Q. And Abbrevio is a midurethral sling?</p> <p>23 A. It's a type of midurethral sling, yes.</p> <p>24 Q. Do you agree with the general proposition</p>	<p style="text-align: center;">Page 69</p> <p>1 is true or not.</p> <p>2 Q. And this paragraph has to do with the</p> <p>3 question of whether polypropylene degrades over time,</p> <p>4 right?</p> <p>5 A. Correct.</p> <p>6 Q. In terms of your report marked as</p> <p>7 Exhibit 1, is this the only report you have written</p> <p>8 in the Ethicon mesh litigation?</p> <p>9 A. I've written three case-specific reports</p> <p>10 as well, patient-specific reports.</p> <p>11 Q. Is that with respect to the MDL or outside</p> <p>12 of the MDL?</p> <p>13 A. That's with respect to the MDL.</p> <p>14 Q. Did you examine those women?</p> <p>15 A. Yes.</p> <p>16 Q. Do you know if they are wave 1 cases?</p> <p>17 A. I do not.</p> <p>18 MS. MARIGLIANO: They are.</p> <p>19 Q. (By Ms. Maimbourg) Have you been deposed</p> <p>20 in those cases?</p> <p>21 A. No.</p> <p>22 MS. MAIMBOURG: Has that been requested?</p> <p>23 Do you know?</p> <p>24 MS. MARIGLIANO: It's not been requested.</p>

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<p>1 Q. (By Ms. Maimbourg) Do you know the names 2 of any of those patients?</p> <p>3 A. I don't -- I don't off the top of my head, 4 no.</p> <p>5 Q. Does Exhibit 1 -- would you like to 6 correct anything in your report, before we start 7 looking at it in detail?</p> <p>8 A. No, I don't believe so.</p> <p>9 Q. I actually have a question to you about 10 it. You are identified as an M.D. on the front page 11 and, in fact, you are not an M.D.; is that true?</p> <p>12 A. Oh, I would like to correct that.</p> <p>13 Q. You're a D.O.</p> <p>14 A. I didn't even notice that.</p> <p>15 Q. And when you signed it, though, you were 16 confirming it was accurate, and that these were the 17 opinions that you were going to give at the trial of 18 this -- any of these cases, to a reasonable degree of 19 medical certainty, right?</p> <p>20 A. Yes.</p> <p>21 Q. On page 8 of your report, you state that 22 you have worked closely with medical device companies 23 in the development and analysis of pelvic repair mesh 24 products. Was that with reference to AMS and what</p>	<p>1 Instructions For Use?</p> <p>2 A. Yes, I believe I did, but mostly for a 3 foreign country, which I think was Japan.</p> <p>4 Q. What was the unique thing about that? I 5 mean, why would you only do that?</p> <p>6 A. They just asked -- because I was involved 7 with -- they wanted the initial Monarc trials. I 8 believe Japan has different regulations that look 9 very closely at the different trials, so they just 10 wanted my input on getting clearance in Japan, and 11 also helping kind of check those, the IFU, and that 12 sort of thing.</p> <p>13 Q. Did you ever draft language for any of the 14 IFUs, in terms of adverse reactions or warnings or 15 precautions?</p> <p>16 A. No, I don't believe so.</p> <p>17 Q. When you were a consultant with AMS, did 18 you draft any professional education materials?</p> <p>19 A. No, I had input into some of the different 20 professional education programs, as far as worked 21 with them on presentations and slide presentations 22 and that sort of thing, but they were -- they were 23 the authors, they developed them.</p> <p>24 Q. In terms of your opinions, now starting on</p>
<p style="text-align: center;">Page 71</p> <p>1 you already previously described?</p> <p>2 A. Yes.</p> <p>3 Q. Have you worked with any other company in 4 that way?</p> <p>5 A. I did some work early on with Tyco -- 6 U.S. Surgical Tyco with the IBS product, did a little 7 bit of work with Caldera, really mostly as a 8 preceptor. And the work we talked about, small 9 amount of work with Gynecare early on as well with 10 TVT.</p> <p>11 Q. In terms of product development, what can 12 you specifically tell me you did?</p> <p>13 A. During the different phases of product 14 development with American Medical Systems, looked at 15 different early prototypes, tested early prototypes, 16 gave feedback on improvements, both in incontinence 17 and prolapse procedures.</p> <p>18 Q. Is that with respect to the obturator 19 product or retropubic product or both?</p> <p>20 A. I was involved with both.</p> <p>21 Q. How about the Mini sling for them?</p> <p>22 A. Yes.</p> <p>23 Q. Did you ever have any involvement in 24 consulting with them as to the content of the</p>	<p style="text-align: center;">Page 73</p> <p>1 page 9, which you have labeled number 1, design 2 defects. The first thing you say in your heading is, 3 Tendency to cause pain, and bladder, bowel, and 4 sexual dysfunction secondary to location of mesh.</p> <p>5 What is it about the location of the mesh 6 that creates this tendency? And if you could be 7 brief, I would appreciate it.</p> <p>8 MS. MARIGLIANO: Object to the form. 9 Answer as completely as you need to.</p> <p>10 THE WITNESS: Well, as briefly as, or as 11 elongated as it may be, specifically, with the 12 transobturator sling or location of the mesh in 13 the periurethral tissues extending out through 14 the obturator muscles, the adductor longus 15 muscles themselves, specifically with the TVT-O 16 having more mesh in the adductor muscles 17 themselves, with that type of placement of the 18 mesh, it's been noted over time that with 19 contraction -- with contraction, ultimately, 20 that can cause pain.</p> <p>21 It then causes pelvic floor dysfunction, 22 because of dyssynergia and spasms throughout the 23 muscles that can affect bowel, bladder function, 24 and sexual function throughout the vagina and</p>

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<p>1 the pelvis.</p> <p>2 Q. (By Ms. Maimbourg) So my question was</p> <p>3 only about the location. So you told me your whole</p> <p>4 opinion, right?</p> <p>5 MS. MARIGLIANO: Object to the form.</p> <p>6 THE WITNESS: Yes, but the location of the</p> <p>7 mesh in the periurethral tissues, as well</p> <p>8 extending out into specifically with the TOT and</p> <p>9 TVT-O, obturator internus, externus adductor</p> <p>10 muscles.</p> <p>11 Q. (By Ms. Maimbourg) So in other words, as</p> <p>12 I understand that, it's where the mesh is lying, and</p> <p>13 it's the technique of getting it there that you are</p> <p>14 calling here as a defect?</p> <p>15 A. Yes, it's not only where the mesh is</p> <p>16 lying, but also how it's placed specifically with the</p> <p>17 TOT-O device, which includes the needles and the mesh</p> <p>18 itself.</p> <p>19 Q. In these two pages, and I'm basically</p> <p>20 going through this the way you have set it up.</p> <p>21 A. Okay.</p> <p>22 Q. So in these two pages, subsection A, am I</p> <p>23 correct that you cite nothing for the proposition</p> <p>24 that the location of the mesh has a tendency to cause</p>	<p>1 Q. (By Ms. Maimbourg) So B --</p> <p>2 MS. MARIGLIANO: Object to the form.</p> <p>3 Q. (By Ms. Maimbourg) B is entitled, Mesh</p> <p>4 Implanted in Groin Muscles Causes Complications, and</p> <p>5 it's essentially one paragraph, right?</p> <p>6 A. Yes.</p> <p>7 Q. And you say here that the mesh -- bottom</p> <p>8 of 10 -- these transverse mesh arms damage the</p> <p>9 levator and obturator and adductor muscles. And so</p> <p>10 I'm going to stop there, and ask you, what is your</p> <p>11 support for that statement that the arms damage those</p> <p>12 muscles?</p> <p>13 A. The subsequent papers and literature that</p> <p>14 have been -- that have described patients that have</p> <p>15 prolonged groin pain, thigh pain, vaginal pain,</p> <p>16 dyspareunia from the mesh arms lying within these</p> <p>17 muscle groups themselves.</p> <p>18 Q. Can you identify those articles?</p> <p>19 A. Sure. I mean, as far as if we want to</p> <p>20 take a look at long-term complications, meaning at</p> <p>21 least pain of any kind of subsequent nature, or</p> <p>22 having pain, then we can start with some of the</p> <p>23 initial trials, the de Leval initial trials that</p> <p>24 basically they relied upon, who's the inventor of the</p>
<p style="text-align: center;">Page 75</p> <p>1 pain, bladder, bowel and sexual dysfunction?</p> <p>2 MS. MARIGLIANO: You're just saying in</p> <p>3 subsection A, you're asking if he said that or</p> <p>4 if he --</p> <p>5 MS. MAIMBOURG: Correct.</p> <p>6 MS. MARIGLIANO: -- didn't include that?</p> <p>7 MS. MAIMBOURG: That's exactly what I'm</p> <p>8 asking, in these two pages.</p> <p>9 MS. MARIGLIANO: I'm just going to object</p> <p>10 to the form.</p> <p>11 THE WITNESS: What I'm describing is</p> <p>12 the -- in those two pages, and it gets into</p> <p>13 specifics as far as where the mesh is implanted</p> <p>14 and how it causes complications at the bottom of</p> <p>15 page 10, and subset of B. In A itself, it's</p> <p>16 just describing the placement of the initial</p> <p>17 TOT, and then the subsequent development of the</p> <p>18 TVT-O, and how that is placed itself.</p> <p>19 Q. (By Ms. Maimbourg) So in these two pages</p> <p>20 under subsection A, you don't cite any medical</p> <p>21 literature for the proposition. You cite that in</p> <p>22 other parts of your report?</p> <p>23 A. Yes.</p> <p>24 MS. MARIGLIANO: Well --</p>	<p style="text-align: center;">Page 77</p> <p>1 product, 26 percent groin pain. They didn't really</p> <p>2 track that out.</p> <p>3 And then as the papers started coming out</p> <p>4 in the literature, including Laurikainen's original</p> <p>5 paper, I think was 2007 in the Green Journal of</p> <p>6 OB/GYN, groin pains of 16 percent at a year,</p> <p>7 5 percent persistent groin pain, which is still</p> <p>8 significantly impacting women at that point in time.</p> <p>9 And then we can list Yik Lim and Marcus Carey, the</p> <p>10 same amount -- actually, 24 percent short-term pain,</p> <p>11 4 percent long-term pain.</p> <p>12 Q. You know what? We'll get into -- are</p> <p>13 these all cited in your report, 'cause --</p> <p>14 A. They are.</p> <p>15 Q. -- we'll probably get into some of them.</p> <p>16 A. They are.</p> <p>17 Q. Do you mind if I move on, and we can talk</p> <p>18 about them as they come up?</p> <p>19 A. Sure.</p> <p>20 Q. All right. I wanted to ask you, though,</p> <p>21 with respect to the definition of prolonged pain,</p> <p>22 which that's the term you used in your answer, could</p> <p>23 you tell me your understanding of what that is versus</p> <p>24 what is postoperative pain? And in your mind, is</p>

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<p style="text-align: right;">Page 78</p> <p>1 there a difference in this analysis?</p> <p>2 A. Yes, I mean, I think really any type of</p> <p>3 postoperative pain should be resolved by six weeks</p> <p>4 and 12 weeks, probably at the latest. Anything that</p> <p>5 is beyond that, I believe becomes more of a prolonged</p> <p>6 pain issue. And certainly something that's going</p> <p>7 beyond six months to one year is more of a persistent</p> <p>8 type of pain issue.</p> <p>9 Q. So at the top of page 11, you say, If pain</p> <p>10 results in the levator ani region secondary to the</p> <p>11 mesh -- what did you mean, secondary to the mesh?</p> <p>12 A. Specifically, if there's a mesh arm in</p> <p>13 that muscle creating contraction, creating fibrosis,</p> <p>14 a chronic inflammatory reaction, that creates</p> <p>15 shrinkage of the mesh in the surrounding tissues that</p> <p>16 creates nerve entrapment or pain for any of those</p> <p>17 reasons, then that's going to ultimately affect the</p> <p>18 muscles throughout the pelvic floor.</p> <p>19 Q. Now, in this paragraph, same paragraph</p> <p>20 where we're talking, you do cite the Cochrane review</p> <p>21 showing -- you say, overall rates of groin pain</p> <p>22 higher in the TOT group, right?</p> <p>23 A. Yes.</p> <p>24 Q. You cite the Cochrane review. Now, does</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. Well, I'll explain to you what I mean.</p> <p>2 Many of the articles you cite here, which I've read,</p> <p>3 refer to possibilities. They use the word "may,"</p> <p>4 they use the word "can," and I have not found in any</p> <p>5 of the articles on your reliance list that you cite,</p> <p>6 where an author in a scientific publication has said,</p> <p>7 to a reasonable degree of medical probability, or</p> <p>8 similar words, that the mesh arms in the muscles are</p> <p>9 causing the type of contraction and scarring that you</p> <p>10 believe, in your opinion, causes the pain. Have I</p> <p>11 missed something, is there an article that does that?</p> <p>12 MS. MARIGLIANO: Object to the form.</p> <p>13 THE WITNESS: Well, I think that basically</p> <p>14 journal articles, and journals themselves, the</p> <p>15 verbiage that is required is different. That is</p> <p>16 what that particular author is stating. They</p> <p>17 also would state that if the mesh wasn't there,</p> <p>18 certainly the patient wouldn't have pain in that</p> <p>19 specific location.</p> <p>20 So there's been multiple studies that have</p> <p>21 looked at anatomical directions of this mesh,</p> <p>22 where it's going, the TVT-O in relationship to</p> <p>23 the obturator nerves. Also saying why are these</p> <p>24 patients in the TVT-Os having more groin pain</p>
<p style="text-align: right;">Page 79</p> <p>1 the Cochrane review give a probable explanation or</p> <p>2 reason for this, or is it just reporting the</p> <p>3 statistics?</p> <p>4 A. The Cochrane review is considered probably</p> <p>5 the kind of leading authority on data analysis from</p> <p>6 high level studies, evaluating all of the literature</p> <p>7 that's been reported.</p> <p>8 Q. So is it just reporting the statistics or</p> <p>9 is it giving a probable explanation?</p> <p>10 A. It reports the statistics.</p> <p>11 Q. So can you cite to me any article -- and</p> <p>12 again, we can maybe get into this, but as you sit</p> <p>13 here right now, in this part of the deposition, can</p> <p>14 you cite to me any article that has verified, through</p> <p>15 a scientific process, your previous answer about how</p> <p>16 the mesh arms in the muscle cause pain through</p> <p>17 various mechanisms, where that has been proven?</p> <p>18 A. I mean, there's many, many articles that</p> <p>19 describe chronic pain in this region secondary to</p> <p>20 TTVT-O slings, and many come up with scientific</p> <p>21 reasoning behind it. So I'm not sure really what</p> <p>22 your -- what your question is, as far as to how you</p> <p>23 can specifically state the kind of scientific</p> <p>24 reasoning behind that.</p>	<p style="text-align: right;">Page 81</p> <p>1 than those that don't have mesh in that specific</p> <p>2 area.</p> <p>3 And so although they may say "may" or</p> <p>4 "perhaps" or "theoretically," which is verbiage</p> <p>5 that journals, medical journals require, it's in</p> <p>6 my opinion, to a medical degree of certainty,</p> <p>7 that this is what's causing these complications.</p> <p>8 Q. (By Ms. Maimbourg) And what is your</p> <p>9 personal opinion based on?</p> <p>10 A. My personal opinion is based on the -- my</p> <p>11 medical training, my experience, my taking care of</p> <p>12 patients with these type of complications, implanting</p> <p>13 and doing research trials on every type of avenue</p> <p>14 that you can with midurethral slings. And knowing</p> <p>15 that we don't see groin pain in patients that have a</p> <p>16 retropubic sling that is similar to this type of a</p> <p>17 pain, when the mesh is in the muscle or irritating</p> <p>18 the nerve directly.</p> <p>19 Q. Doctor, on page 12 of your report, when</p> <p>20 we're talking about pain syndromes, one of the</p> <p>21 articles you cite several times in your report is</p> <p>22 Teo. Did I say that right? Is it -- it's T-E-O?</p> <p>23 A. Correct. I'm not sure of the</p> <p>24 pronunciation.</p>

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<p>1 Q. I was wondering if we could go off the 2 record for a minute, so you could locate that in your 3 binder?</p> <p>4 MS. MARIGLIANO: We can -- it's -- oh, 5 it's in there.</p> <p>6 THE WITNESS: No, it's right here.</p> <p>7 MS. MAIMBOURG: I don't how long it's 8 going to take.</p> <p>9 (Discussion off the record.)</p> <p>10 Q. (By Ms. Maimbourg) What is the 11 publication date on the bottom, to the right?</p> <p>12 A. 2011.</p> <p>13 Q. No, the month?</p> <p>14 A. April.</p> <p>15 Q. All right, so -- 'cause you have February 16 cited here, and I wanted to make sure that I have the 17 same article. Let me see yours, just to make sure 18 it's the same as mine. Yes, it is. Okay. Doctor, 19 I'm actually going to mark my copy, so you can put 20 yours back in your notebook?</p> <p>21 (Exhibit 17 was marked for 22 identification.)</p> <p>23 Q. (By Ms. Maimbourg) And you describe on 24 page 12 of your report that this trial by Teo -- do</p>	<p>1 Q. The second paragraph that says, during 2 recruitment? Are you there?</p> <p>3 A. Uh-huh.</p> <p>4 Q. This paragraph says, During recruitment, a 5 few studies were published showing similar cure rates 6 for the two procedures, meaning obturator and 7 retropubic, but a high incidence of leg pain in 8 patients after receiving a transobturator tape. 9 After discussing these data at an investigator 10 meeting, we decided to stop recruitment before the 11 full calculated sample was recruited, since it was 12 deemed that clinical equipoise had been lost?</p> <p>13 A. Correct.</p> <p>14 Q. So the study was not stopped, as you 15 state, because of excess pain reports in the TVT-O 16 arm; is that true?</p> <p>17 A. I believe it was due to the pain that they 18 were seeing as well as the discussion they had based 19 on that, and the literature that was in the -- that 20 had been being published.</p> <p>21 Q. Well, in fact, that's not what that 22 paragraph says under Results, does it?</p> <p>23 A. No, but I believe in the discussion, they 24 talk about that as well.</p>
<p style="text-align: center;">Page 83</p> <p>1 you think that's how he pronounces it? T-E-O? How 2 would you pronounce that? You don't know?</p> <p>3 A. I would have say Teo.</p> <p>4 Q. Teo. All right. So you say in your 5 report on page 12, This trial -- I believe you're 6 talking about this trial, Teo -- was perhaps the 7 clearest example of the clinical and scientific 8 impact of pain syndromes caused by the TVT-O, and 9 comes from the results of an independent study that 10 was performed by several of Ethicon's KOLs. So 11 that's what you're referring to, Teo, right?</p> <p>12 A. Yes.</p> <p>13 Q. Now, you say in your report that the 14 investigators stopped the trial, because of excess 15 pain reports in the TVT-O arm, and you put in 16 parentheses, 26.4 percent pain reported at six 17 months, right?</p> <p>18 A. Yes.</p> <p>19 Q. And I think you actually referred to that 20 in one of your previous answers. So I'd like you to 21 go to page 1351 of the article, under the section 22 that's entitled, Results. Are you there? Results, 23 1351?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">Page 85</p> <p>1 Q. And then you say in your report that the 2 authors concluded it was no longer ethical to use the 3 TVT-O device, given the clear negative impact on 4 patient health. And if you look at the Results 5 section, where we just were a minute ago -- you're 6 there, you're on the right page.</p> <p>7 A. Okay.</p> <p>8 Q. It says, We believed it was no longer 9 ethical to randomize women to the TVT-O arm, in light 10 of these published studies --</p> <p>11 A. Correct.</p> <p>12 Q. -- but data on women already recruited 13 would be of value, right? Those two sentences are 14 different, are they not?</p> <p>15 A. They're saying that those -- that it would 16 still be of value, that they were already -- that 17 those patients were already implanted and 18 certainly -- but they're not going to implant 19 anymore, they're not going to recruit anymore. So I 20 don't know whether or not these patients had already 21 been implanted or not.</p> <p>22 Q. I guess it would be an unfair reading of 23 your report for anyone to believe that you were 24 saying here that the authors of this article believed</p>

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<p>1 it was unethical to use the TVT-O device, that would 2 be an unfair reading of your statement. 3 MS. MARIGLIANO: Object to the form. 4 Q. (By Ms. Maimbourg) Right? 5 A. I think that what the authors are saying 6 is that they believe that it's unethical to implant 7 and/or recruit any more patients to continue this 8 patient trial, and implant anymore TVT-Os. And that 9 based on their review of the literature and their 10 initial findings of a very high amount of groin pain 11 in those patients. 12 Q. All right. In the conclusion of the 13 article, on page 1355, the authors state, Short-term 14 cure rates at six months are similar for the two 15 procedures. TVT-O results in a higher level of 16 postoperative and leg pain, although these problems 17 are transient. And then it says, The two procedures 18 have a high cure rate with a low rate of 19 complications, right? Right? 20 A. Yes, that's what it states. 21 Q. All right. So you, in your report, 22 several times quote a concluding message that I 23 cannot find in this article. And that concluding 24 message says, in your report, page 12, Given the</p>	<p>1 THE WITNESS: It may be, or it's in 2 quotations. 3 Q. (By Ms. Maimbourg) Well, take a look at 4 page 40 of your report, where you also quote this 5 article by Teo, the concluding message? 6 A. Okay. 7 Q. Are you on page 40 looking at it? 8 A. Uh-huh. 9 Q. Does that look like a quote to you? The 10 way it's set off, single-spaced indented? 11 A. Again, I don't know specifically if this 12 paragraph was supposed to be a quote directly from 13 the article. 14 Q. In terms of the leg pain, you say here, 15 this -- we're on page 13 in your report, This article 16 was not the first to show that TVT-O caused leg, 17 groin, thigh pain in more than one in four women who 18 were implanted, right? 19 A. Yes. 20 Q. And this study that we've been talking 21 about, the Teo study, involved 127 women. And, in 22 fact, if you look at the page 1354, they do say that 23 leg pain was experienced by 26.4 percent of women in 24 the TVT-O group, right?</p>
<p style="text-align: center;">Page 87</p> <p>1 comparable efficacy of the procedures, it seems 2 preferable to recommend retropubic tape placement to 3 avoid a high incidence of leg pain. Can you tell me 4 where in the article it says that? 5 MS. MARIGLIANO: I'm going to object. 6 He's not saying he's quoting that. 7 Q. (By Ms. Maimbourg) Well, can you tell me, 8 even if you're not quoting it, can you tell me where 9 in the article, the authors state, it seems 10 preferable to recommend retropubic tape placement, or 11 is that your conclusion, your own concluding message? 12 A. I mean, I'd have to go through this, you 13 know, kind of line by line to take a look at 14 the -- the last paragraph -- to take a look at, you 15 know, their exact verbiage throughout the thing. I 16 don't know if I'm quoting them, if you're saying you 17 don't see those exact words throughout there, I'll 18 take your word on that. But if -- that was my 19 conclusion as well as their summaries of their 20 discussion and their results. 21 Q. (By Ms. Maimbourg) So if you quote 22 something usually in your report, you would have it 23 as a single-spaced indented quote, right? 24 MS. MARIGLIANO: Object to the form.</p>	<p style="text-align: center;">Page 89</p> <p>1 A. Yes. 2 Q. And the article also says, The problem 3 resolves spontaneously within three months, right? 4 A. Correct. 5 Q. And that would be within the postoperative 6 period that you previously defined? 7 A. Yes, in their particular study. 8 Q. So this study, in particular, does not 9 support your statement, or your claim that this leg 10 and groin pain can be severe, chronic, life-long, and 11 debilitating, does it? 12 MS. MARIGLIANO: Object to the form. 13 THE WITNESS: Not the particular study, 14 but if you continue on in the discussion, they 15 do have verbiage that does talk about those 16 concerns. And actually, a couple of the papers 17 we just talked about, including Laurikainen, as 18 well as Yik Lim, as well as the Latthe meta 19 analysis as well. 20 Q. (By Ms. Maimbourg) This study does not 21 give any support for your claim that it's the 22 proximity of the sling to nerves that is responsible 23 for causing the pain, does it? 24 MS. MARIGLIANO: Object to the form.</p>

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<p style="text-align: right;">Page 90</p> <p>1 THE WITNESS: This study basically shows 2 that when you place mesh tape into the groin 3 muscles, it can cause a significant amount of 4 albeit postoperative pain in this particular 5 patient population, but also lead to longer 6 periods of pain that's been shown in other 7 studies.</p> <p>8 Q. (By Ms. Maimbourg) The purpose of this 9 study was not to prove that, and it doesn't show it, 10 right?</p> <p>11 MS. MARIGLIANO: Object to the form.</p> <p>12 THE WITNESS: Well, the purpose of this 13 study may have been to prove it, and take a 14 look, but they stopped the study, and didn't 15 look at patients beyond six months.</p> <p>16 Q. (By Ms. Maimbourg) I'm not talking -- my 17 last question, I apologize if it was not clear, but I 18 really wasn't talking about longevity. I was talking 19 about mechanism.</p> <p>20 A. Okay.</p> <p>21 Q. And, you know, the authors of this article 22 talk about possibilities, and they don't talk 23 about -- they don't give an opinion in this article, 24 and they don't prove an opinion as to what is causing</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. So researcher -- researchers are 2 fundamentally scientists, right?</p> <p>3 A. Yes.</p> <p>4 Q. And they deal in possibilities and 5 probabilities?</p> <p>6 A. They do. And when they're writing for --</p> <p>7 Q. I didn't have a question.</p> <p>8 A. Okay.</p> <p>9 Q. And, in fact, in your report, you say your 10 opinions you hold to a reasonable degree of medical 11 certainty, I think you used the term, right?</p> <p>12 A. Yes.</p> <p>13 Q. And you're not giving opinions to 14 possibilities, right?</p> <p>15 A. I'm giving opinions, based on a reasonable 16 degree of medical certainty, which in this instance, 17 we're taking a look at risk versus benefits, and 18 risks outweighing benefits with the TVT-O procedure.</p> <p>19 And some of these journals hold a higher degree of 20 probability and require that to be able to say 21 certain verbiage. So this is why investigators will 22 say these types of -- utilize this type of language 23 in their studies.</p> <p>24 Q. So maybe if these authors had put in the</p>
<p style="text-align: right;">Page 91</p> <p>1 this postoperative pain, is that true?</p> <p>2 MS. MARIGLIANO: Object to the form.</p> <p>3 Q. (By Ms. Maimbourg) The only statements 4 are on page -- at the top of 1355, talk -- talks in 5 terms of possibilities?</p> <p>6 A. Yeah, and they -- but they do go on to say 7 that cadaveric studies have revealed that the tape 8 passes much closer to the obturator nerve using the 9 inside-out than the outside technique. This could 10 possibly cause the obturator nerve to be more 11 susceptible to damage, inflammation and edema, 12 resulting in pain. Neuropathy resulting in gait 13 abnormality and numbness has also been reported, and 14 seems to be associated more with the inside-out 15 technique.</p> <p>16 So I think they are giving their opinions 17 as to what the cause of pain is in this TTV-O 18 procedure.</p> <p>19 Q. So they're talking about possibilities 20 here, correct? That's the word they use?</p> <p>21 A. They are certainly talking about 22 possibilities and utilizing their expertise in being 23 researchers, clinicians, experts in urogynecology to 24 say what is the potential cause of this pain.</p>	<p style="text-align: right;">Page 93</p> <p>1 word probable, their article may not have been 2 accepted, because it would not have passed the 3 peer-review process, because it's bad science, right?</p> <p>4 MS. MARIGLIANO: I'm going to object to 5 the form. You're confusing legal verbiage with 6 verbiage that's using medical in articles.</p> <p>7 MS. MAIMBOURG: You're not allowed to make 8 speaking objections, I'm sorry.</p> <p>9 MS. MARIGLIANO: So that's my objection.</p> <p>10 THE WITNESS: Well, we don't know that.</p> <p>11 Q. (By Ms. Maimbourg) We don't know that. 12 We would be speculating, right?</p> <p>13 A. Yes.</p> <p>14 Q. So let's move on to page 13 through 24 of 15 your report, which is the next section, quite long. 16 And it's entitled, Inside-Out Technique of TTV-O 17 Increases Risk of Nerve Injury/Pain. So when I look 18 at this section, particularly page 14, and I'm 19 looking kind of down here at the bottom, I think what 20 you're saying here is that the technique of inserting 21 the TTV-O puts it too close to certain nerves, which 22 could actually damage the nerve at implantation or be 23 close enough, so that fibrosis around the mesh could 24 very easily cause nerve damage and pain. Does that</p>

24 (Pages 90 to 93)

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<p>1 sort of summarize what you're saying about this 2 inside-out technique?</p> <p>3 MS. MARIGLIANO: I'm just going to object 4 to the form.</p> <p>5 THE WITNESS: It's -- yes, it's talking 6 about one aspect of the -- of the pain.</p> <p>7 Q. (By Ms. Maimbourg) And this defect has to 8 do with the technique of implanting the product. And 9 in this particular part of your opinion, you're not 10 talking about the product itself, you're talking 11 about the technique of implanting?</p> <p>12 A. Well, I'm talking about the product, 13 because the product involves the implantation process 14 of going from the inside-out. It's part of the 15 product, it's part of the device as all -- all of the 16 different components of it are.</p> <p>17 Q. So you're defining the technique as the 18 same as the product?</p> <p>19 A. The technique is part of the product. 20 This particular product was the only one that was 21 developed to go from inside to outside. And 22 specifically, the way that it's placed, including all 23 of the components of the product, including the metal 24 wing tip guide, the needles, the mesh, the sheath are</p>	<p>1 article that you've quoted, and I'd like you to go to 2 page 1205, so we can read the rest of the quote. 3 Could you go to page 1205, I'm sorry. 4 A. 1205 is the first page. 5 MS. MARIGLIANO: Look up here 6 (indicating). 7 THE WITNESS: Okay. Got it. Okay. 8 Q. (By Ms. Maimbourg) The column on the 9 left, I'm going to show you mine. See this green, 10 that's where you quoted? 11 A. Okay. 12 Q. Okay. And I'm going to after that 13 quote. After the quote about the MAUDE database, 14 Dr. Hinoul says that the MAUDE database needs to be 15 interpreted cautiously, as no incidence rate can be 16 derived from them, and reporting bias cannot be 17 accounted for. 18 Do you agree with that, with respect to 19 the MAUDE database? 20 A. I would agree that incident rate cannot be 21 derived from them, and reporting bias also cannot be 22 accounted for. 23 Q. And then he goes on to cite an article by 24 Debodinance that was a non-randomized prospective</p>
<p style="text-align: center;">Page 95</p> <p>1 all part of the procedure. 2 Q. Right, but you're -- the title of this 3 section of your report is, The Technique of TTVT-O 4 Increases Risk of Nerve Injury/Pain, right? That's 5 how you titled it? 6 A. Correct. 7 Q. All right. And in part of this section, 8 you quote an article by Piet Hinoul, and I believe 9 you say on page 15 -- well, take a look at what you 10 say there. Are you there in the report? 11 A. Yes. 12 MS. MARIGLIANO: I'm not there. Oh, 13 you're talking about on page 15, okay, I see. 14 Q. (By Ms. Maimbourg) So you quote him 15 to -- that he states that, The suspicion that the 16 inside-out procedure is linked to more neurological 17 injuries was already raised in de Leval's original 18 article. A recent review of the data collected by 19 the MAUDE database also implies more pain, et cetera, 20 et cetera, right? 21 A. Yes. 22 (Exhibit 18 was marked for 23 identification.) 24 Q. (By Ms. Maimbourg) I'm handing you that</p>	<p style="text-align: center;">Page 97</p> <p>1 study compared outside-in Monarc to inside-out TTVT-O, 2 and found no difference in thigh pain between both 3 groups, right? 4 A. He did. 5 Q. And that -- and that article would be 6 contrary to your opinions in this case that the 7 inside-out approach causes an increase of pain over 8 the outside-in, right? 9 MS. MARIGLIANO: Object to the form. 10 THE WITNESS: Not necessarily. I mean, 11 there's one study that he quotes, and there's 12 probably a couple more that show the same amount 13 of groin pain in the inside-out versus the 14 outside-in. However, there's multiple -- more 15 studies that also show an increased amount of 16 pain with the inside-out versus the outside-in. 17 So he's quoting one particular study and 18 there may be a couple more, but I can probably 19 quote more studies overall that show a higher 20 rate of pain with inside-out TTVT-O versus 21 outside-in approach. 22 Q. (By Ms. Maimbourg) You did not choose to 23 put the Debodinance article in your report, because 24 it doesn't support your opinions, right?</p>

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1	1 MS. MARIGLIANO: Object to the form.
2	2 THE WITNESS: The Debodinance article is
3	3 part of the list of papers that's in
4	4 my -- that's in -- that's in my reliance list.
5	5 Q. (By Ms. Maimbourg) Was that one that you
6	6 put there, or did the plaintiffs give it to you?
7	7 A. The Debodinance? I don't know.
8	8 Q. You also talk about the Haddad article on
9	9 page 15 and 16?
10	10 A. Yes.
11	11 Q. You have a lot of quotes from there. I'll
12	12 pull it out and mark it, but -- if you want. It
13	13 seems to me that all the quotes that you have here
14	14 are merely the author's regurgitation of certain
15	15 articles, and do not scientifically establish the
16	16 truth of anything they're saying.
17	17 MS. MARIGLIANO: Object to the form.
18	18 THE WITNESS: Well, I wouldn't say --
19	19 again, I mean, we're getting into these
20	20 discussions about what's science and what's
21	21 truth, and what's a reasonable degree of
22	22 certainty. That's the verbiage that's used in
23	23 literature and journals versus the degree of
24	24 certainty of what they -- they might have
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1	1 opinions on. What they're doing here is showing
2	2 all of the different literature supporting their
3	3 findings and their views as well, and discussing
4	4 these issues and complications.
5	5 Q. (By Ms. Maimbourg) Doctor, that article
6	6 had to do with BMI, and it didn't even reach
7	7 statistical significance, right?
8	8 A. I don't know that per se, as far as the
9	9 statistical significance.
10	10 Q. And all of these statements actually had
11	11 nothing to do with their -- the purpose of their
12	12 study, they were just giving background right?
13	13 MS. MARIGLIANO: Object to the form.
14	14 THE WITNESS: Again, correct, they were
15	15 talking about -- you said they were just
16	16 regurgitating other papers, but not saying
17	17 anything scientifically. I think that they're
18	18 supporting -- when one writes a discussion to a
19	19 paper, they're supporting either their theories
20	20 or other theories with different papers in the
21	21 literature.
22	22 Q. (By Ms. Maimbourg) So on the next page,
23	23 when you talk about -- well, we're on 16 and 17. I
24	24 didn't mean it skip too far ahead. You cite two
(Exhibit 19 was marked for	1 identification.)
2	3 Q. (By Ms. Maimbourg) So if we look at the
4	5 Collinet article, which I've placed before you as
6	7 Exhibit 19, this study did not look at long-term
8	9 pain, as far as I know, because if you look on page
10	11 713, they're talking about four to 12 weeks. Maybe I
11	12 missed something, but this does not appear to be a
12	13 long-term pain article.
13	14 A. Residual pain of 2.7 percent.
14	15 Q. It says, up above, postoperative
15	16 complications occurring immediately after surgery, or
16	17 by the first follow-up visit, four to 12 weeks, are
17	18 shown in table 3. And table 3, residual pain,
18	19 2.7 percent. So the Collinet article is not about
19	20 long-term pain.
20	21 A. Right, they quote residual pain at 12
21	22 weeks, yes.
22	23 Q. On page 18, of your report -- are you
23	24 there?
24	25 A. Yes.
25	26 Q. Right about here (indicating), Ethicon
26	27 should never have released an inside-out technique?
27	28 A. Okay.

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<p>1 Q. Do you see that? That that's your 2 opinion, right? 3 A. Yes. 4 Q. And this is what we've been talking about 5 here, they should never have released a -- this 6 technique, right? 7 A. The inside-out technique is the TVT-O, so 8 that's what I'm referring to. 9 Q. Now, you cite to Doctor -- or Professor 10 de Leval's supposed statements on page 18. And just 11 to be clear, you're citing an internal report, where 12 someone is reporting what Dr. de Leval said, right? 13 A. Yes. 14 Q. Is that what it appears to be? 15 A. Yes. 16 Q. And you have this in single-spaced 17 paragraph indented, which would imply it's a quote. 18 Did you mean to imply it was a quote? 19 A. Yes. 20 Q. And do you practice evidence-based 21 medicine in your job as a urogynecologist and 22 surgeon? 23 A. Yes, I try to. 24 Q. Do you consider internal company documents</p>	<p>1 memorandums to sales reps and to doctors, did you 2 ever tell them to do that? 3 A. I think they did distribute a lot to sales 4 reps, probably not to doctors. And I think I would 5 tell them, and did tell them that anything that they 6 had in their internal documents that pertained to 7 patient safety or information that doctors could 8 utilize or needed to utilize, that they should be 9 forthright and forthcoming with all of that 10 information. 11 Q. Is there anything you, in particular, 12 remember that -- content-wise, that you thought they 13 should have taken from their internal e-mails and 14 distributed to doctors? 15 A. No, not specifically. 16 MS. MARIGLIANO: When you get to a decent 17 stopping point -- I can wait a little while, 18 just want to give a heads up. 19 MS. MAIMBOURG: We'll finish one more 20 section. 21 Q. (By Ms. Maimbourg) On page 18 and 19, I'm 22 going to ask you various questions about these 23 statements here, and ask what the support is for 24 them, okay?</p>
<p style="text-align: center;">Page 103</p> <p>1 and e-mails to be a part of evidence-based medicine? 2 A. I think that it's a part of good medicine 3 to know all the information that you can know, so it 4 may ultimately become part of evidence-base medicine. 5 Q. You've implanted devices, other than 6 pelvic mesh? 7 A. Yes. 8 Q. Can you give me an example? 9 A. The InterStim device. 10 Q. Okay, that's a good one. Let's talk about 11 InterStim. Either before implanting your first one, 12 or at any time in your practice, have you ever asked 13 the manufacturer the InterStim to give you their 14 internal memos and e-mails regarding the development 15 of the product? 16 A. No, but we expect the representatives of 17 that company to be forthright and forthcoming with 18 any and all information that they may have about 19 their product, pluses or minuses, negatives or 20 positives. 21 Q. When you were a consultant to AMS 22 regarding Monarc, did you ever tell the people you 23 were working with that they should distribute their 24 internal company e-mails and their internal</p>	<p style="text-align: center;">Page 105</p> <p>1 A. Okay. 2 Q. So you say, As the suburethral portion and 3 the arms of the TVT-O mesh scar in, the tissues 4 surrounding the mesh contract or shrink, which can 5 entrap nerves, deform the vagina and pelvic anatomy, 6 and cause severe chronic pain as the chronic 7 inflammation and foreign body reaction to the mesh 8 continues. 9 And you have a footnote 2 -- end note, I 10 guess I'd call that. Is all of -- everything that 11 you believe supports that statement, is that in that 12 footnote? 13 MS. MARIGLIANO: Object to the form. 14 Q. (By Ms. Maimbourg) Or do you want to add 15 anything? 16 A. No, I mean, I think that you also have to 17 add the breadth of literature that's done primarily 18 on mesh contraction, scar plating, foreign body 19 reaction, fibrosis, nerve entrapment, the works of 20 Cobb, Kling, Klosterhalfen, and all of that body of 21 work. That's a portion of that body of work that's 22 quoted and referenced there, but certainly it's not 23 all of it. 24 Q. The second statement that says, the TVT-O</p>

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<p>1 arms pull unevenly, what is your support for that?</p> <p>2 A. That's based just on my -- you know, my 3 clinical experience, as well as taking care of 4 patients with complications, and seeing contraction 5 more on one side or the other that seems to cause 6 undue amount of pain on that side. And also in 7 patients that have extrusions and erosions in that 8 area, it seems to have been in those instances 9 pulling unevenly on that side.</p> <p>10 Q. And I don't think I ever asked you. You 11 have never implanted a TVT-O in a live patient, 12 right?</p> <p>13 A. I have not.</p> <p>14 Q. The third sentence says, As this 15 inevitable shrinkage occurs, the TVT-O mesh arms pull 16 on the obturator and levator ani. Is that also based 17 on your clinical experience?</p> <p>18 A. That's based on my clinical experience, as 19 well as multiple papers in the literature describing 20 different pain syndromes in patients that have 21 transobturator slings or transobturator approach to 22 pelvic floor meshes, with arms going through same 23 exact tract as the transobturator slings, and 24 describing things like actually syndromes, mesh</p>	<p>1 these types of complications, as well as multiple 2 reports and papers in the literature describing the 3 exact type of syndromes that -- that women with 4 transobturator approach slings, meshes that suffer 5 pain from are -- are under growing.</p> <p>6 Q. Can you name one of those articles?</p> <p>7 A. Yeah, Bruce Finer and Chris Maher talk 8 specifically about the mesh contraction syndrome, 9 sidewall to sidewall.</p> <p>10 Q. Is that in your reliance materials?</p> <p>11 A. I'm not sure it is.</p> <p>12 Q. All right. I'll check it on the break.</p> <p>13 And then the next sentence, and this is the last one 14 before we take a break, it says, When pressure is 15 placed on the mesh during normal activities, it is 16 transmitted to the attachments in the pelvic 17 sidewall, which also deforms and pulls on the muscle 18 at the attachment points, causing significant pain. 19 Would that be that Maher and Fine -- Fine --</p> <p>20 MS. MARIGLIANO: Finer.</p> <p>21 Q. (By Ms. Maimbourg) Finer article, or is 22 there your personal experience, or what is that based 23 on?</p> <p>24 A. Again, it's not only just my personal</p>
<p style="text-align: center;">Page 107</p> <p>1 contraction syndromes that cause exactly this.</p> <p>2 Q. So you use those -- because those women in 3 those studies have a transobturator pain, and they 4 have a transobturator sling, and they have leg pain, 5 you are making a causal connection between the two?</p> <p>6 MS. MARIGLIANO: Object to the form.</p> <p>7 THE WITNESS: Well, this isn't just 8 talking about leg pain as well. This is talking 9 about pain contraction syndromes throughout the 10 pelvic floor musculature and levator ani.</p> <p>11 Q. (By Ms. Maimbourg) Right, but the 12 connection you're making, I want to just understand 13 your opinions, is these women have a transobturator 14 sling that went inside-out, and they have pain, and 15 therefore, you are connecting the two.</p> <p>16 MS. MARIGLIANO: Object to the form.</p> <p>17 Q. (By Ms. Maimbourg) Right?</p> <p>18 A. I am connecting the two, yes.</p> <p>19 Q. And then you say, this force on the pelvic 20 sidewall muscles causes pain during routine daily 21 life activities, like sexual intercourse or 22 defecation. Is that -- what is that based on?</p> <p>23 A. Again, it's based on my clinical 24 experience of dealing with hundreds of patients with</p>	<p style="text-align: center;">Page 109</p> <p>1 experience, it's not only the Maher, Finer, you know, 2 published report, it's also Mickey Karram's paper on 3 mesh complications, it's Sandip Vasavada from the 4 Cleveland Clinic talking about mesh complications in 5 patients they're seeing, it's Hillary Cholhan's 6 paper, which I know that's referenced in here that 7 talks about transobturator slings causing an 8 increased amount of pain versus a retropubic 9 approach, because of this banding perirethrally 10 sidewall to sidewall muscles pulling on the muscles 11 in women that ultimately suffer from that. That was 12 majority of the findings that they had in patients as 13 well.</p> <p>14 MS. MAIMBOURG: All right, let's take a 15 break.</p> <p>16 (A recess was taken.)</p> <p>17 Q. (By Ms. Maimbourg) So we're back on the 18 record. Doctor, in your report, you have identified 19 Abbrevio as a safer option to the TVT-O, right?</p> <p>20 A. Yes.</p> <p>21 Q. And why is that your opinion?</p> <p>22 A. It's my opinion based on, again, clinical 23 experience with smaller mesh tape slings, meaning a 24 shorter amount of mesh, and dealing with the various</p>

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<p>1 type of different slings. So basically, my clinical 2 background, as well as studies in the literature, as 3 well as Ethicon's own internal documents, basically 4 confirming that there's less risk of groin pain and 5 issues with the sling that does not go all the way 6 through the groin muscles.</p> <p>7 Q. The studies in the literature, would those 8 be studies that show what -- what particular studies 9 in the literature? Are they all cited here in your 10 report?</p> <p>11 A. They should be. I mean, specifically, 12 there's been several studies that have been 13 comparative trials with Abbrevio versus TVT-O. And 14 all showing various amounts of decreased risk of 15 groin pain, both in short-term and some in the 16 long-term. Specifically, the paper from Brown, and 17 Shaw and Rardin showing the fact that you have 9 18 percent rate of groin pain with the TVT-O versus 19 1 percent in Abbrevio. And 25 percent of those 20 patients that had groin pain in the TVT-O required a 21 groin dissection. So I mean, you weigh those 22 risk/benefits and clearly the TVT-O -- Abbrevio looks 23 like that it's a much safer alternative.</p> <p>24 Q. From your extensive review of the Ethicon</p>	<p>1 implanted before July 1 of 2010, that Abbrevio was not 2 a safer option for her because the product was not 3 cleared?</p> <p>4 A. Correct.</p> <p>5 Q. Since it's your opinion that Abbrevio is a 6 safer option than TVT-O, I would assume that you have 7 no criticism of its design; is that true?</p> <p>8 A. I still am critical of passing needles 9 through the groin. I still believe that a Mini sling 10 that does not have to be passed -- anything passed 11 through the groin, including needles, would be a 12 safer alternative, as long as the clinical efficacy 13 and the safety is there as well with that procedure. 14 So I'm not sure if I would go as far as I don't have 15 any criticisms of the design of the Abbrevio.</p> <p>16 Q. Well, might you show up in a case 17 criticizing Abbrevio, where a plaintiff is claiming 18 injuries? I mean, would it go that far?</p> <p>19 MS. MARIGLIANO: Object to the form. Go 20 ahead.</p> <p>21 THE WITNESS: At this point in time, no, I 22 don't believe that would be the case.</p> <p>23 Q. (By Ms. Maimbourg) Do you have any 24 criticisms of the polypropylene mesh that is used in</p>
<p style="text-align: center;">Page 111</p> <p>1 documents provided to you, do you know when the 2 product went into development?</p> <p>3 A. The product initially was basically 4 Professor de Leval --</p> <p>5 Q. I'm looking for a date.</p> <p>6 A. The first time that it was brought up was 7 2004.</p> <p>8 Q. When was it cleared by the FDA?</p> <p>9 A. I believe 2009.</p> <p>10 Q. The date I have is July 1st, 2010?</p> <p>11 A. Okay.</p> <p>12 Q. Would you perhaps accept my 13 representation?</p> <p>14 A. Sure.</p> <p>15 Q. Do you agree that Abbrevio could not have 16 been implanted before it was cleared by FDA?</p> <p>17 A. I do. I believe as well, though, that it 18 could have been developed and approved a whole lot 19 before 2009.</p> <p>20 Q. Do you agree that -- understanding what 21 you're saying, you're saying that Ethicon should have 22 put it into development sooner, but would you agree 23 that if one of these plaintiffs in a case in which 24 you've been identified as a general expert was</p>	<p style="text-align: center;">Page 113</p> <p>1 the Abbrevio?</p> <p>2 MS. MARIGLIANO: Object to the form.</p> <p>3 THE WITNESS: I believe any criticism that 4 I have of the mesh of TVT-O would be the same 5 criticisms that I would have of it for the 6 Abbrevio. I believe that since it's not as long, 7 that there's a potential for less contraction 8 and less kind of stretching out and curling and 9 roping of the sling, which would be a positive 10 for Abbrevio.</p> <p>11 Q. (By Ms. Maimbourg) So when you were 12 implanting the AMS devices, before they were removed 13 from the market, they are polypropylene mesh slings, 14 right?</p> <p>15 A. Correct.</p> <p>16 Q. And you didn't have any safety concerns 17 about implanting that polypropylene mesh, did you?</p> <p>18 A. No.</p> <p>19 Q. Do you know anything about the difference 20 between the polypropylene in -- in that Sparc sling 21 and the polypropylene in any of the Ethicon products?</p> <p>22 A. No.</p> <p>23 Q. Now, in terms of the Abbrevio being a safer 24 option, I know you relied on certain company</p>

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<p>1 documents that you cite here. Is any one of them 2 more important to you than another, as you sit here?</p> <p>3 A. What pages are we on now, or was it 4 included -- or where are we going through?</p> <p>5 Q. Actually, I don't know. You know what, 6 I'm going to withdraw that question. We don't have 7 the time.</p> <p>8 A. Okay.</p> <p>9 Q. Let's look at page 22. You see on the 10 bottom, you say -- last paragraph, you say, these 11 studies all show?</p> <p>12 A. Yes.</p> <p>13 Q. That paragraph, or that first sentence, is 14 that kind of like a good summary of your opinions? 15 You can just read it to yourself.</p> <p>16 MS. MARIGLIANO: I'm going to object to 17 the form.</p> <p>18 Q. (By Ms. Maimbourg) Well, only one of your 19 opinions. In other words -- I'll ask a different 20 question.</p> <p>21 You're saying here that the studies you've 22 quoted show that the original TVT-O device was 23 defective in design as to its procedural steps, the 24 length of the mesh, the location of the exit point of</p>	<p>1 And my question to you is -- I guess I'll find that 2 -- oh, it's on 23, bottom of the first paragraph. 3 You see that sentence?</p> <p>4 A. Yes.</p> <p>5 Q. When you use the word, safer, I just want 6 to make sure I understand what you mean by that. Do 7 you mean less long-term pain or less postoperative 8 pain, or both?</p> <p>9 A. Both.</p> <p>10 Q. And that would be with respect to the 11 comparative studies you already talked about today, 12 at least one of the bases for that, right?</p> <p>13 A. Yes.</p> <p>14 Q. So the next section is about the defects 15 of the device itself, and you talk about the mesh 16 being twice the width of the hole in the tissue that 17 the needle and cannula create to pass the mesh 18 through the obturator and adductor muscles, right?</p> <p>19 A. Yes.</p> <p>20 Q. And you say that this causes folding and 21 deformation of the mesh?</p> <p>22 A. Yes.</p> <p>23 Q. Does it cause that folding and deformation 24 of the mesh, in your opinion, throughout the length</p>
<p style="text-align: center;">Page 115</p> <p>1 the needles, and the risk of injury to the obturator 2 and location of the mesh, right?</p> <p>3 A. Yes.</p> <p>4 Q. These lead, in your opinion, to an 5 increased risk of postoperative groin pain, which you 6 have defined as within the first six to 12 weeks, 7 right?</p> <p>8 A. Postoperative time frame, yes.</p> <p>9 Q. And then also adductor, obturator, and 10 levator ani pain. And you say, This type of pain can 11 lead to up-regulation of the nerves to these muscles 12 and the remainder of the pelvic floor resulting in 13 spasms, vaginal pain, pain with intercourse, and 14 bladder and bowel dysfunction. What is the basis for 15 your opinion on that regard?</p> <p>16 A. Again, the same basis of my opinions that 17 we talked about on the previous issues with the 18 contraction of the mesh from sidewall to sidewall, 19 creating banding, creating pain, creating contraction 20 of the muscles, and ultimately, creating this sort of 21 dysfunction as well. So it has to do with all of 22 those studies that we've already talked about.</p> <p>23 Q. On page 22, you state, Ethicon continued 24 to sell, despite evidence that Abbrevio was safer.</p>	<p style="text-align: center;">Page 117</p> <p>1 of the mesh?</p> <p>2 A. It at least does upon its entry into the 3 muscles and through the muscles in the leg itself.</p> <p>4 Q. Is that -- is it -- is that the only 5 place? I didn't -- I can't remember what you said in 6 the beginning, you said at least at that point.</p> <p>7 A. Well, minimally, it does at that point, 8 because it could ultimately lead to the mesh not 9 lying flat under the urethra as well, but initially, 10 minimally, yes, it's going to roll and curl upon 11 itself from the point of entry into the muscle all 12 the way through the leg.</p> <p>13 Q. And you base this on the fact that you 14 have implanted TVT slings, and you have implanted 15 TVT-O slings in fresh cadaver specimens, right?</p> <p>16 A. Yes.</p> <p>17 Q. And how many cadaver specimens were 18 involved in what you did?</p> <p>19 A. Probably three or four.</p> <p>20 Q. Where did you get the measurements?</p> <p>21 A. Which measurements?</p> <p>22 Q. The ones you quote, about the cannula and 23 the hole in the tissue?</p> <p>24 A. I believe these were internal documents</p>

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<p>1 from Ethicon.</p> <p>2 Q. Would this same defect also be present in</p> <p>3 Abbrevio?</p> <p>4 A. Yes, but again, not -- for a very much</p> <p>5 shorter distance, though.</p> <p>6 Q. And when you were implanting Monarc, and</p> <p>7 you were a consultant for AMS, did you know those</p> <p>8 dimensions? In other words, did you know the size,</p> <p>9 the width of the mesh compared to the needle holes?</p> <p>10 A. No, not the exact width -- or not the</p> <p>11 exact width of the needle, or they also had a</p> <p>12 dilating tip on their mesh as well, that was designed</p> <p>13 to kind of try to prevent some of that, to actually</p> <p>14 dilate the tract, so that the mesh would lie flatter.</p> <p>15 Q. After you implant a sling, are you able to</p> <p>16 detect through your examination with your finger if</p> <p>17 the mesh is lying flat?</p> <p>18 A. Under the urethra, yes.</p> <p>19 Q. And I think you say later in this section</p> <p>20 that this deformation causes scarification and</p> <p>21 contraction. Would your support for that be the same</p> <p>22 articles you just told me about?</p> <p>23 A. Yes, and looking at evidence of</p> <p>24 contraction and scarring and fibrosis.</p>	<p>1 those reasons.</p> <p>2 (Exhibit 20 was marked for</p> <p>3 identification.)</p> <p>4 Q. (By Ms. Maimbourg) Doctor, I've marked as</p> <p>5 Exhibit 20, the Weisberg memo that you referred to in</p> <p>6 your report. Just take a quick look at it. So this</p> <p>7 memo, and I don't mean to interrupt you if you're not</p> <p>8 done, has to do with fraying. Is this what you're</p> <p>9 suggesting that this sheath technology does, it frays</p> <p>10 the mesh? That's what you said, right?</p> <p>11 A. This is specifically talking about fraying</p> <p>12 itself. I don't know if it's talking about sheath</p> <p>13 technology. It's talking about stretching the tape</p> <p>14 and the amount of stretch that it requires to fray.</p> <p>15 Q. Well, you say in your report, Dr. Marty</p> <p>16 Weisberg noted as well that tension exacerbates mesh</p> <p>17 fraying?</p> <p>18 A. Right.</p> <p>19 Q. And then Marty Weisberg also says that</p> <p>20 there is no reason to expect that the fraying of the</p> <p>21 mesh or the particles generated would create any</p> <p>22 safety risks?</p> <p>23 A. Right, it's clinically relevant, as noted</p> <p>24 above, meaning that if the sheath was not pulling off</p>
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<p>1 Q. On page 25, you talk about -- you call</p> <p>2 this sheath technology?</p> <p>3 A. Yes.</p> <p>4 Q. You know what I'm referring to when I say</p> <p>5 that?</p> <p>6 A. Yes.</p> <p>7 Q. And I think you say it's clinically</p> <p>8 relevant, right?</p> <p>9 A. Yes.</p> <p>10 Q. And it's clinically relevant to what,</p> <p>11 causing pain?</p> <p>12 A. I think causing pain, causing urinary</p> <p>13 obstructive symptoms, creating immediate tension that</p> <p>14 one would not desire at the time of the procedure,</p> <p>15 that ultimately could lead to some of these different</p> <p>16 issues.</p> <p>17 Q. And are you, by citing to Marty Weisberg's</p> <p>18 memo here, are you suggesting that Marty Weisberg has</p> <p>19 confirmed that this sheath technology issue is</p> <p>20 clinically relevant?</p> <p>21 MS. MARIGLIANO: Object to the form.</p> <p>22 THE WITNESS: I believe that that was --</p> <p>23 actually came out of an e-mail from him, stating</p> <p>24 that it was clinically relevant, secondary to</p>	<p>1 correctly and stretching the tape and having</p> <p>2 increased friction as the tape -- as the sheath was</p> <p>3 trying to be pulled off the tape, that would cause it</p> <p>4 to stretch and cause it to fray. So that's the</p> <p>5 relation to it being clinically relevant.</p> <p>6 Q. But Marty Weisberg is not saying it's</p> <p>7 clinically relevant?</p> <p>8 MS. MARIGLIANO: Object to the form.</p> <p>9 THE WITNESS: Marty Weisberg is saying</p> <p>10 that if you stretch the tape, it frays out.</p> <p>11 Q. (By Ms. Maimbourg) But he's not saying</p> <p>12 it's clinically relevant, is he?</p> <p>13 A. Correct.</p> <p>14 MS. MARIGLIANO: What are you saying is</p> <p>15 "it," the fraying?</p> <p>16 MS. MAIMBOURG: Right.</p> <p>17 Q. (By Ms. Maimbourg) I mean, I asked you</p> <p>18 why you cited this, and I'm just exploring it. So</p> <p>19 let's move on. Can you cite any medical literature</p> <p>20 for why this sheath technology, which you say causes</p> <p>21 stretching, fraying, and roping, why it's clinically</p> <p>22 relevant?</p> <p>23 A. Yes, and I think I do down here just a</p> <p>24 little bit, which was the Dietz paper that took a</p>

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<p>1 look at postoperative urinary obstructive type 2 symptoms between the Sparc and TTV procedure. Again, 3 the Sparc procedure has a tensioning suture 4 throughout it. I believe there's another study by 5 Moalli that looked at the different stretch 6 properties of the different meshes. The TTV mesh is 7 the one that stretches the most. It deforms the 8 most, it elongates, and it stays elongated.</p> <p>9 So if that's happening during that time 10 frame, then it's going to cause increased obstructive 11 type symptoms, which Dietz showed in his paper, as 12 well if it's been shown before as well with the 13 folding, the curling, and that sort of thing, and 14 mesh being contracted like that, that it can lead to 15 increased risk of extrusion, erosion, and those 16 issues as well.</p> <p>17 Q. Does the Dietz article talk about pain?</p> <p>18 A. It does not.</p> <p>19 Q. On page 26 of your report, at the bottom, 20 you say, The blind passage of the trocars is 21 unreasonably dangerous. Do you use those terms, 22 unreasonably dangerous, in your every day practice?</p> <p>23 A. I wouldn't say that I wouldn't use them, 24 so yeah, there's times that I would use those words,</p>	<p>1 Piet Hinoul prior to him joining Gynecare. 2 Q. Is that the study we talked about earlier? 3 A. Yes. 4 Q. Are you talking about, in this sentence, 5 injury upon implantation or later nerve injury due to 6 fibrosis? 7 A. Both. 8 Q. So your next statement about the shape of 9 the needle and passing it causes the user to exit 10 much more lateral in the leg, you can't be basing 11 that on your personal experience, because you haven't 12 implanted in a patient, right? 13 MS. MARIGLIANO: Object to the form. 14 THE WITNESS: Not in a live patient, but 15 in a fresh frozen cadaver specimen, I have in 16 direct comparison to outside-in needles. So I 17 do have experience passing these type of 18 needles, and it was the reason why I decided 19 never to perform a TTV-O in a live patient. 20 Q. (By Ms. Maimbourg) And when did you do 21 those cadavers? 22 A. Back in the 2005/6 time frame. 23 Q. What was the circumstance? 24 A. It was a cadaver lab at the AMS facility,</p>
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<p>1 yes.</p> <p>2 Q. And you say, It presents the unnecessary 3 risk of tissue damage, vascular damage, nerve damage, 4 and internal trauma. What is the support for that 5 statement?</p> <p>6 A. Again, that statement is based on my 7 clinical experience, my education, my training, my 8 years of doing research on midurethral tape slings, 9 and seeing and treating complications of patients 10 with those types of complications.</p> <p>11 Q. Your next statement says, The helical 12 shape of the needle itself and the original technique 13 described leads to a much higher risk of obturator 14 nerve injury compared to an outside-in technique. 15 And your support for that is what?</p> <p>16 A. Again, all of the different articles in 17 the literature that we've reviewed that we've taken a 18 look at, that talk about increased risk of 19 postoperative and long-term pain, as well as the 20 different anatomic studies that were done that are 21 quoted in my report as well, talking about the 22 reproducibility of passing the TTV-O needle and 23 various risks to the obturator nerve branches, even 24 following the IFU guidelines, including one done by</p>	<p>1 training. 2 Q. So you were, as an AMS preceptor and 3 consultant, comparing a competitor product to your 4 own? 5 A. It wasn't my own product. And again, if 6 you take a look at the products that I used 7 throughout the year -- throughout the years, I didn't 8 use the Sparc product. When they didn't have a 9 retropubic sling, I used a retropubic TTV sling. So 10 what I wanted to do, at any point in time in my 11 career, is if there were new products out, I wanted 12 to be able to utilize and take a look at them, and 13 utilize my own judgment to see if this is something 14 that I should be doing instead of an outside-in 15 approach. 16 So it had nothing to do with -- with them 17 saying, can you look at this and find negatives in 18 it compared to our sling. It was for my own good to 19 say, okay, what are the pluses and negatives of an 20 alternative approach, because if you've got something 21 better, then I'm going to use that. 22 Q. Was this just you, or was it a group of 23 docs? 24 A. I'm not sure who was there. It wasn't a</p>

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<p>1 training session per se, so I think there may have 2 been a few different physicians there, trying 3 different products.</p> <p>4 Q. Was it more an R&D?</p> <p>5 A. I think there was some R&D folks there, 6 yeah.</p> <p>7 Q. And since it was held by AMS, certainly 8 the purpose of it was not to talk about the virtues 9 of TTVT-O and the inside-out approach.</p> <p>10 MS. MARIGLIANO: Object to the form.</p> <p>11 Q. (By Ms. Maimbourg) Right?</p> <p>12 A. I think that -- I wouldn't say that. I 13 would say that I think AMS, as a company as well, 14 wanted to look into all competitive products to see, 15 are they missing something. This is the only 16 company, Gynecare, that was going from the inside to 17 the outside with the TTVT-O.</p> <p>18 I think they also wanted to know 19 internally, is there advantages to this, and let's 20 get our experts to take a look at it, and tell us 21 whether it is or not. My personal reasons for 22 wanting to do that was what I explained before.</p> <p>23 Q. All right. And so were you one of those 24 experts who were called in by AMS to decide if this</p>	<p>1 A. Right. I mean, my personal preference 2 would be to have mechanically cut mesh that is not 3 going to stretch out during implantation or removal 4 of the sheath. And a tensioning suture in that mesh 5 helps prevent that. I don't even know -- the 6 interesting thing is that it's -- until I was made 7 aware of some of these things about laser cut versus 8 mechanical cut, I was never informed of any of these 9 changes that they had made through this in TTVT, and 10 that both were available, and we might have one 11 version versus another version at our hospital.</p> <p>12 Q. So it's your belief that TTVT was offered 13 both as mechanical and laser cut?</p> <p>14 A. I believe it is.</p> <p>15 Q. Do you know which is used in Abbrevio?</p> <p>16 A. I do not.</p> <p>17 Q. So when you decided that Abbrevio was a 18 safer option to TTVT-O, it didn't really matter to you 19 whether the mesh was laser cut or mechanical cut?</p> <p>20 A. I think it's a less of issue for Abbrevio 21 for the reasons we've described before as well. It's 22 a much smaller piece of mesh. It's much less apt 23 to -- you don't have to pull that mesh through as 24 much tissue. There's 85 percent less mesh, so you're</p>
<p style="text-align: center;">Page 127</p> <p>1 was something they should look into? Is that what 2 you're representing that meeting to be?</p> <p>3 A. No. I think you have to understand during 4 different cadaver lab sessions, whether it was for -- 5 to have consultants there to look at their products, 6 new products, whether there was a training going on. 7 They also had access to other products and 8 competitive products, and so you had the opportunity 9 to take a look at these things.</p> <p>10 Q. Okay. On page 27 and 28 of your report, 11 you talk about mechanical cut and laser cut mesh?</p> <p>12 A. Yes.</p> <p>13 Q. In summary, both are bad, right?</p> <p>14 According to your report, both are bad?</p> <p>15 A. Well, I mean, I think that with the laser 16 cut, I think the thought was, we can make the mesh 17 stiffer, we can help prevent the stretching and the 18 immediate fraying, and the immediate kind of roping 19 of the mesh. However, with the laser cut, it also 20 showed that there was higher rates of extrusions in 21 certain products that had that in. So I think they, 22 you know, both had negative aspects to them.</p> <p>23 Q. Well, you outlined for both, the negative 24 aspects, right?</p>	<p style="text-align: center;">Page 129</p> <p>1 going to get less issues with stretching, curling, 2 and putting on tension immediately.</p> <p>3 Q. Do you believe in medical innovation?</p> <p>4 A. Yes, I do.</p> <p>5 Q. That's why you do clinical trials 6 probably, right?</p> <p>7 A. Yes.</p> <p>8 Q. In terms of your failure to warn opinions 9 that begin on page 48, are all of the TTVT-O training 10 materials that you reference there on your reliance 11 list?</p> <p>12 A. I believe so, yes.</p> <p>13 Q. You said here, I have also reviewed IFUs 14 for many other medical products. Which ones?</p> <p>15 A. Well, I mean, those would be products that 16 I've utilized throughout the years, so all those AMS 17 products we've talked about, other products that I've 18 implanted.</p> <p>19 Q. Are there any that you reviewed for 20 purposes of becoming a consultant in this litigation?</p> <p>21 A. No. Well, not for this one, but I've 22 reviewed IFUs for the Bard litigation.</p> <p>23 Q. So you became familiar with the Bard IFU 24 as you worked as a consultant?</p>

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<p>1 A. Yes, unless I had implanted any of those 2 products.</p> <p>3 Q. Had you?</p> <p>4 A. The Avaultas, no. Nor the sling.</p> <p>5 Q. How about the Boston Scientific products, 6 I think you had said you -- had you implanted an 7 Obtryx?</p> <p>8 A. No.</p> <p>9 Q. So you became familiar with Boston 10 Scientific's IFU for a sling through your work as a 11 medical/legal consultant?</p> <p>12 A. Yes.</p> <p>13 Q. And you became familiar with the TTV-O IFU 14 because of your work as a medical consultant -- 15 medical/legal consultant?</p> <p>16 A. Yes.</p> <p>17 Q. On page 29 of your report, you say, 18 Physicians must be able to reasonably rely upon 19 product IFUs to make informed decisions. That's your 20 belief and opinion, right?</p> <p>21 A. Yes, I believe it's one of the things 22 that -- that you need to make an informed decision, 23 yes.</p> <p>24 Q. Right, so you'll agree the IFU is not an</p>	<p>1 Q. Do you agree that a manufacturer does not 2 need to tell a surgeon about the basics of sterile 3 technique when doing surgery?</p> <p>4 A. No, that would be inherent to their 5 training.</p> <p>6 Q. So we don't -- and Ethicon doesn't have to 7 tell surgeons to wash their hands, because if they 8 don't, it could cause a fatal infection, right?</p> <p>9 A. Correct.</p> <p>10 Q. And manufacturers don't have to tell 11 surgeons that they need to consider the type of 12 anesthesia that the patient has to have before 13 surgery?</p> <p>14 A. Correct.</p> <p>15 Q. And a manufacturer doesn't have to tell a 16 surgeon about the different risks of different 17 surgical positions a patient could be put in?</p> <p>18 A. No, I disagree with that one, because 19 specifically if the position is critical for 20 placement of that product or procedure that is going 21 to make it safer or decrease risk of complications, 22 then yes, they are -- they should be responsible for 23 relaying that information to physicians.</p> <p>24 Q. You state in your report that a physician</p>
<p style="text-align: center;">Page 131</p> <p>1 exclusive source of information about medical devices 2 for doctors who are going to implant them?</p> <p>3 A. No, it's not exclusive device or -- but 4 it's an important one.</p> <p>5 Q. You meant exclusive source?</p> <p>6 A. Yes, I'm sorry.</p> <p>7 Q. Doctors, before they implant a medical 8 device, they should read the pertinent medical 9 literature, should they not?</p> <p>10 A. Yes, they should.</p> <p>11 Q. And they should achieve competency before 12 they implant a device?</p> <p>13 A. Yes.</p> <p>14 Q. Doctors also have sources of information, 15 such as product training offered by manufacturers, 16 right?</p> <p>17 A. Yes, if it's offered.</p> <p>18 Q. And they can go to CMEs to learn about the 19 area of medicine in which they practice, and most 20 CMEs may touch on devices, right?</p> <p>21 A. Yes.</p> <p>22 Q. And certainly, doctors can rely on their 23 own experience in learning about a medical device?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">Page 133</p> <p>1 must be warned of a frequent -- of the frequency, 2 severity, duration, and potential permanence of 3 adverse events by a manufacturer. That is your 4 opinion, correct?</p> <p>5 A. Yes.</p> <p>6 Q. What is the basis for your opinion that a 7 manufacturer should warn of frequency, severity, 8 duration, and potential permanence?</p> <p>9 A. I think it's the surgeon's right to have 10 that information at their hands, to be able to offer 11 treatments and be forthcoming and forthright to their 12 own patients, so that the patients can understand the 13 risks and complications of any procedure they may be 14 undergoing. So if that information is available to a 15 manufacturer, then certainly it needs to be relayed 16 to the physician and patients.</p> <p>17 Q. When you were a consultant for AMS, did 18 you advocate that position to them?</p> <p>19 A. Yes.</p> <p>20 Q. And did they put frequency, severity, 21 duration, and potential permanence into their IFU?</p> <p>22 MS. MARIGLIANO: Object to the form.</p> <p>23 THE WITNESS: I don't know about that. I 24 know during any type of professional education</p>

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<p>1 training that I did for them, we certainly 2 relayed all of that information to the 3 physicians.</p> <p>4 Q. (By Ms. Maimbourg) Right, so a 5 manufacturer can pass on information in ways other 6 than in the IFU, right?</p> <p>7 A. Sure, but you weren't asking me initially 8 whether it was just in the IFU. You said, should 9 they give this information.</p> <p>10 Q. Okay. My fault. So just so I'm clear 11 you're not saying that the IFU, to be adequate, must 12 include frequency, severity, duration, and potential 13 permanence of adverse events?</p> <p>14 A. I am saying, yes, it should be included in 15 the IFU.</p> <p>16 Q. All right. And my question to you, then, 17 is, when you were at -- when you were assisting AMS 18 as a consultant, are you aware of whether AMS ever 19 included that type of this information in the IFUs 20 for its sling products?</p> <p>21 A. I'm not aware specifically. I don't 22 recall the IFU details specifically.</p> <p>23 Q. And since you've read all the literature 24 in that big binder before you, what should those</p>	<p>1 A. Sure. So they probably should include a 2 variety of numbers, from 1 percent to 30 percent.</p> <p>3 Q. That's your opinion?</p> <p>4 A. Yes.</p> <p>5 Q. Is it your opinion that the Instructions 6 For Use should include a statement about mesh 7 degradation?</p> <p>8 MS. MARIGLIANO: Object to the form.</p> <p>9 MS. MAIMBOURG: Can you tell me how I can 10 cure that objection?</p> <p>11 MS. MARIGLIANO: You said how -- number 12 one, I don't think he's offering any opinions 13 about degradation.</p> <p>14 MS. MAIMBOURG: Okay. If he's not, then 15 that's swell.</p> <p>16 Q. (By Ms. Maimbourg) Are you offering any 17 opinions about degradation?</p> <p>18 A. No.</p> <p>19 Q. Are you offering any opinions about 20 excessive and chronic foreign body reaction?</p> <p>21 A. Where are we looking at right now, or are 22 we?</p> <p>23 Q. I'm just asking, in general, are you going 24 to give expert opinions about polypropylene mesh used</p>
<p style="text-align: center;">Page 135</p> <p>1 numbers in the IFU be today for, let's say, the TVT 2 retropubic as to the frequency of anything you want 3 to pick right now, any adverse event?</p> <p>4 MS. MARIGLIANO: Object to the form.</p> <p>5 THE WITNESS: I think that it needs to be 6 basically consistent with what's in the 7 literature, what's in -- within the Cochrane 8 reviews, the meta analysis, their own internal 9 studies, their own documents. They've got 10 internal studies that haven't been published 11 before.</p> <p>12 So whatever information they have, they 13 should produce that, risk of mesh extrusion for 14 the retropubic TVT seems to be generally in the 15 range of 1 to 2.5 percent. That should be 16 listed. So any of that information that's 17 there, it should be in there.</p> <p>18 Q. (By Ms. Maimbourg) You would agree, 19 though, that the literature is quite varied as to 20 how -- strike that.</p> <p>21 You would agree with me that if you were 22 going to go look for the frequency of a particular 23 adverse event in the medical literature, you would 24 find a variety of numbers?</p>	<p style="text-align: center;">Page 137</p> <p>1 in TVT-O, causing excessive and chronic foreign body 2 reaction?</p> <p>3 A. Only in relation to any type of chronic 4 inflammatory effects, scarring, that occurs that 5 would ultimately create pain from nerve or muscle 6 damage.</p> <p>7 Q. Are you saying that should be in the IFU?</p> <p>8 A. I think if they have evidence of a chronic 9 inflammatory response, and not a transitory 10 inflammatory response, then that should be included 11 in the IFU, yes.</p> <p>12 Q. And based on everything you've reviewed, 13 did Ethicon have that evidence?</p> <p>14 A. Yes.</p> <p>15 Q. And is what -- the evidence they had, is 16 it included in your report at page 30?</p> <p>17 A. Yes. Or actually, probably, I think it's 18 on the next page as well.</p> <p>19 Q. So you're quoting testimony from Piet 20 Hinoul and Charlotte Owens. Is there anything else 21 that you're relying on for your opinion?</p> <p>22 A. I think that if you get to like tab number 23 20, on page 33, it gets into more of some of the 24 different studies that were both in their internal</p>

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<p>1 documents, as well as meetings with Klosterhalfen, 2 who Professor Klosterhalfen was one of their 3 consultants, but did a lot of publishing in the 4 literature about chronic inflammatory reactions, mesh 5 contraction, and subsequent issues with pain and 6 nerve entrapment.</p> <p>7 Q. On page 32, you talking about the 2015 8 Instructions For Use?</p> <p>9 A. Yes.</p> <p>10 Q. With respect to TVT-O, correct? And you 11 say, all of these risks were known to Ethicon before 12 2015?</p> <p>13 A. Uh-huh.</p> <p>14 Q. Is that a yes?</p> <p>15 A. I'm sorry, yes.</p> <p>16 Q. Can you say that these risks were not 17 known to doctors before 2015, can you say that?</p> <p>18 MS. MARIGLIANO: Object to the form.</p> <p>19 THE WITNESS: I can say that some of these 20 risks were probably not known to some or many 21 doctors.</p> <p>22 Q. (By Ms. Maimbourg) Some doctors knew them 23 all, right?</p> <p>24 MS. MARIGLIANO: Object to the form.</p>	<p>1 is a permanent implant, and significant dissection 2 may be required if the mesh needs to be removed. 3 That could cause -- that this could cause, you know, 4 permanent -- even more permanent, more pain, and more 5 nerve damage that's permanent to the leg. In 6 addition, saying that there's no guarantee that all 7 the mesh can be removed, or any of the complications 8 caused by the mesh would be reversed by some -- a 9 major operation like that.</p> <p>10 Q. Anything else?</p> <p>11 A. I don't believe so.</p> <p>12 Q. So in this section of the report, you have 13 many things that -- and I don't have the time to 14 actually go through every one of them, that Ethicon 15 should have warned about. And I want to be clear, 16 are you saying that warning should have come in the 17 Instructions For Use?</p> <p>18 A. Yes.</p> <p>19 Q. And if a doctor had gone through Ethicon 20 training, and had learned it in training, but it was 21 not in the IFU, would you feel that Ethicon had met 22 its duty to warn?</p> <p>23 MS. MARIGLIANO: Object to the form.</p> <p>24 THE WITNESS: No, because not all</p>
<p style="text-align: center;">Page 139</p> <p>1 THE WITNESS: Yes.</p> <p>2 Q. (By Ms. Maimbourg) You knew them all 3 before they were put in the IFU, right?</p> <p>4 A. Yes.</p> <p>5 Q. Have you done any surveys of doctors, or 6 do you have any kind of base of knowledge to know 7 what doctors who are implanting slings know or don't 8 know?</p> <p>9 A. Only based upon my experience of training 10 and professional education of hundreds of doctors at 11 various levels, in talking with them, and figuring 12 out what they know and don't know, but no formal 13 surveys, no.</p> <p>14 Q. Is the 2015 IFU for TVT-O adequate, in 15 your opinion?</p> <p>16 A. I think the only thing that I would add to 17 this would be the fact that it talks about needing 18 multiple surgeries to remove the mesh, but it doesn't 19 talk about the fact that it could be impossible to 20 remove all the mesh, and that should be noted.</p> <p>21 Q. Anything else to make it adequate?</p> <p>22 A. I would also say the mesh is a permanent 23 implant, significant dissection may be -- as a 24 continuation of the -- the line that says, the mesh</p>	<p style="text-align: center;">Page 141</p> <p>1 physicians went through training. And Gynecare 2 didn't require that training to be done through 3 them. So somehow those risks have to be put out 4 to the physicians, whether it's in an IFU, 5 whether they're there at professional education, 6 whether they're risks or complications that are 7 occurring that they're finding out about after 8 launch, a letter to physicians to -- for 9 notification. So somehow, that has to get out.</p> <p>10 Q. (By Ms. Maimbourg) On some of these 11 warnings, on page 32 and 33, so bottom of 32, top of 12 33, you're referring to the de Leval data. And 13 you're saying that that data showed that it was, in 14 some instances, chronic and severe. And the de Leval 15 data that you had cited earlier was not long-term 16 data, so I'm wondering, what was it that you were 17 relying on for that opinion?</p> <p>18 A. What page are we looking at?</p> <p>19 Q. Bottom of 32, top of 33. You say, the 20 de Leval data which showed it, leg pain?</p> <p>21 A. Right.</p> <p>22 Q. Was not rare, was not transient, was not 23 limited to the leg, and was, in some instances, 24 chronic and/or severe?</p>

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<p>1 A. I mean, it was shown later in his trial 2 with Waltregny that it wasn't transient, it was 3 severe in some cases. So I believe that's what I was 4 referring to.</p> <p>5 Q. And again, chronic means what to you?</p> <p>6 A. Chronic means lasting longer than six 7 months.</p> <p>8 Q. When you were implanting the Monarc sling, 9 what were the complications you were seeing in your 10 patients?</p> <p>11 MS. MARIGLIANO: Object to the form.</p> <p>12 THE WITNESS: We saw complications of mesh 13 extrusion, urinary obstruction, urinary urgency 14 frequency, dyspareunia, or pain with 15 intercourse. Luckily, I didn't have any of my 16 own patients that suffered from groin pain, so 17 that wasn't really an issue. So those were the 18 major complications.</p> <p>19 Q. (By Ms. Maimbourg) With respect to the 20 Sparc sling that you're using now, what have been the 21 complications that you're seeing in your own 22 patients?</p> <p>23 MS. MARIGLIANO: Object to the form.</p> <p>24 THE WITNESS: The RetroArc.</p>	<p>1 A. Yes.</p> <p>2 Q. They ought to be in every IFU for every 3 sling, right?</p> <p>4 A. Yes.</p> <p>5 Q. On the inadequate physician training 6 issue, on page 39, you -- it's a short section, but 7 you talk about the e-mail from Marianne Kaminski?</p> <p>8 A. Uh-huh.</p> <p>9 Q. Right? Yes?</p> <p>10 A. Yes.</p> <p>11 Q. And so I guess to sum it up, this message 12 is perhaps -- well, let me see what you say. The 13 company intended to have sales representatives train 14 physicians on the TVT-O procedure, right? That's 15 what you say?</p> <p>16 A. Yes.</p> <p>17 Q. Do you know for a fact that sales reps 18 trained doctors how to implant TTVT-O?</p> <p>19 A. Yes.</p> <p>20 Q. Who is that?</p> <p>21 A. I don't know specific -- I mean, I just 22 know in discussions from reps that I've known that 23 have -- that have utilized -- you know, worked in 24 this field, discussions with them, discussions with a</p>
<p style="text-align: center;">Page 143</p> <p>1 Q. (By Ms. Maimbourg) Did I say that wrong?</p> <p>2 A. You said the Sparc. Sparc means top-down. 3 RetroArc means the same sling from bottom-up.</p> <p>4 Q. Then I apologize, and I meant the 5 RetroArc?</p> <p>6 A. The same.</p> <p>7 Q. The same that you just listed?</p> <p>8 A. Yes.</p> <p>9 Q. Any groin pain?</p> <p>10 A. No.</p> <p>11 Q. Do you believe that the IFU for the 12 RetroArc is adequate?</p> <p>13 A. I haven't looked at it critically.</p> <p>14 Q. Would you hold this same opinion as to all 15 of the warnings that you say should have been in the 16 Ethicon TTVT-O IFU -- let me strike that, and ask a 17 different question.</p> <p>18 Putting the groin pain aside, you have a 19 lot of opinions here about different things that 20 should have been in the TTVT-O IFU, would you agree 21 with me?</p> <p>22 A. Yes.</p> <p>23 Q. Do you agree that those same warnings 24 ought to be in the RetroArc IFU?</p>	<p style="text-align: center;">Page 145</p> <p>1 rep that used to work for Gynecare, that he did end 2 up, you know, training physicians, yes.</p> <p>3 Q. So I'm not interested in the sales reps 4 for any other company, but I do want to know the name 5 or names of any Gynecare rep that you are relying on 6 for this statement?</p> <p>7 A. Marquel Fleetwood.</p> <p>8 Q. Mark?</p> <p>9 A. Marquel.</p> <p>10 Q. Is that M-A-R --</p> <p>11 A. Q-U-E-L.</p> <p>12 Q. And what's his last name?</p> <p>13 A. Fleetwood.</p> <p>14 Q. And he was a Gynecare rep?</p> <p>15 A. He was.</p> <p>16 Q. He was your rep?</p> <p>17 A. Yeah, I believe he was for a period of 18 time. He's worked with different companies, but he 19 started with Gynecare, yes.</p> <p>20 Q. And he told you, just so I'm clear when I 21 interview him, you're saying under oath that he told 22 you that he trained doctors how to implant TTVT-Os 23 himself?</p> <p>24 A. Yes.</p>

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1 Q. How many times did he do it? 2 A. I don't know. 3 Q. And he -- you didn't misinterpret what he 4 said, because he wasn't saying that he sent them to 5 training, you're saying he trained them? 6 MS. MARIGLIANO: Object to the form. 7 THE WITNESS: I'm saying that he went to a 8 physician's operating room who had never done a 9 TVT-O before, and walked them through it, or a 10 TVT procedure, yes. 11 Q. (By Ms. Maimbourg) Was it TVT or TVT-O? 12 A. I don't know which -- which it was. 13 Q. And you know the credentialing for 14 procedures is done by hospitals, not by medical 15 device manufacturers? 16 A. Correct. 17 Q. And that's across the board in the 18 United States, right? 19 A. Yes. 20 Q. So that physician obviously was 21 credentialed by his or her hospital to do that 22 procedure? 23 A. He should have been, yes. 24 MS. MARIGLIANO: I think you have about	1 - - - - - 2 E R R A T A 3 - - - - - 4 PAGE LINE CHANGE 5 REASON: _____ 6 REASON: _____ 7 REASON: _____ 8 REASON: _____ 9 REASON: _____ 10 REASON: _____ 11 REASON: _____ 12 REASON: _____ 13 REASON: _____ 14 REASON: _____ 15 REASON: _____ 16 REASON: _____ 17 REASON: _____ 18 REASON: _____ 19 REASON: _____ 20 REASON: _____ 21 REASON: _____ 22 REASON: _____ 23 REASON: _____ 24 REASON: _____
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1 four or five minutes. 2 Q. (By Ms. Maimbourg) I think I'm just about 3 at the end of my time, so I'm going to ask a general 4 question. You know, obviously, this is a long 5 report, and I had a limited amount of time. I tried 6 to hit the big points. 7 A. Okay. 8 Q. I guess I'd like to ask you if there is 9 any major opinion that I missed, or any major paper 10 that you're going to rely on, or any particular 11 document that I should spend my last four minutes on? 12 MS. MARIGLIANO: I'm just going to object 13 to the form of that question. 14 THE WITNESS: I don't believe so. 15 Q. (By Ms. Maimbourg) Okay. Would you like 16 to read the transcript, or would you like to waive 17 your right to read the transcript? 18 A. Read it, please. 19 MS. MARIGLIANO: We'll read it. 20 MS. MAIMBOURG: Okay. So we're done. 21 MS. MARIGLIANO: This deposition is 22 concluded. 23 (Deposition concluded at 1:00 p.m.)	1 2 ACKNOWLEDGMENT OF DEPONENT 3 4 I, _____, do 5 hereby certify that I have read the 6 foregoing pages, and that the same is 7 a correct transcription of the answers 8 given by me to the questions therein 9 propounded, except for the corrections or 10 changes in form or substance, if any, 11 noted in the attached Errata Sheet. 12 13 14 ROBERT D. MOORE, D.O. DATE 15 16 Subscribed and sworn 17 to before me this 18 _____ day of _____, 20 _____. 19 My commission expires: _____ 20 21 22 Notary Public 23 24

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1 DIS CLO SURE
2

3 STATE OF GEORGIA) DEPOSITION OF
4 CLAYTON COUNTY) ROBERT D. MOORE, D.O.
5

6 Pursuant to Article 10.B of the Rules and
7 Regulations of the Board of Court Reporting of the
8 Judicial Council of Georgia, I make the following
9 disclosure:

10 I am a Georgia Certified Court Reporter. I am
11 here as a representative of Golkow Technologies.
12

13 Golkow Technologies was contacted by the offices
14 of Tucker Ellis to provide court reporting services
15 for this deposition. Golkow Technologies will not be
16 taking this deposition under any contract that is
17 prohibited by O.C.G.A. 9-11-28 (c).

18 Golkow Technologies has no contract or agreement
19 to provide court reporting services with any party to
20 the case, or any reporter or reporting agency from
21 whom a referral might have been made to cover the
22 deposition.

23 Golkow Technologies will charge its usual and
24 customary rates to all parties in the case, and a
financial discount will not be given to any party in
this litigation.

21 F. Renee Finkley, RPR, RMR, CRR, CLR
22 Georgia CCR-B-2289
23
24

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1 C E R T I F I C A T E
2 STATE OF GEORGIA:
3 COUNTY OF CLAYTON:

4 I, F. Renee Finkley, a Certified Court
5 Reporter in and for the State of Georgia, do hereby
6 Certify:

7 That prior to being examined, the witness
named in the foregoing deposition was by me duly
sworn to testify to the truth, the whole truth, and
nothing but the truth.

8 That said deposition was taken before me
9 at the time and place set forth and was taken down by
me in shorthand and thereafter reduced to
10 computerized transcription under my direction and
supervision, and I hereby certify the foregoing
deposition is a full, true and correct transcript of
11 my shorthand notes so taken.

12 I further certify that I am not of kin or
counsel to the parties in the case, and I am not in
13 the regular employ of counsel for any of the said
parties, nor am I in any way financially interested
in the result of said case.

14 IN WITNESS WHEREOF, I have hereunto
subscribed my name this 15th day of April, 2016.

15
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19 F. Renee Finkley, RPR, RMR, CRR, CLR
20 Georgia CCR-B-2289
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39 (Pages 150 to 151)

Golkow Technologies, Inc. - 1.877.370.DEPS

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